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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

Licensing Committee Report

Ruth Conroy, Pharm.D., Chair
Richard Benson, Public Board Member
Clarence Hiura, Pharm.D.
John Jones, RPh

Report of September 21, 2005

ACTION

ACTION ITEM 1

That the Board of Pharmacy approve the proposed statutory change B & P Code § 4127.1 to issue a temporary pharmacy permit for a change of ownership to pharmacies that compound injectable sterile drug products.

Discussion
A pharmacy that compounds injectable sterile drug products is required to have a specialized pharmacy permit in addition to being licensed as a pharmacy. Under current law, when a pharmacy changes ownership, the board has the authority to issue a temporary pharmacy permit during the transition from the previous owner to the new owner. However, this same provision was not included for the injectable sterile compounding pharmacies. This has caused some difficulties for pharmacies that can obtain a temporary pharmacy permit for their general pharmacy practice, but cannot obtain temporary permit for the compounding of sterile injectable sterile products. Thus, the pharmacy must cease this service until the change of ownership is completed.

The committee was provided with proposed statutory language that would allow for the issuance of a temporary pharmacy permit when a change of ownership occurs for pharmacies that compound injectable sterile drug products. **(Attachment A)**

If the board approves the proposed statutory changes, they would be introduced in 2006 as omnibus provisions in legislation.

ACTION ITEM 2

That the Board of Pharmacy recognize the School of Pharmacy at Touro University.

Discussion
Touro University College of Pharmacy is requesting that the Board of Pharmacy recognize its school of pharmacy for purposes of approving intern applications for its 64 students in the Class of 2009.

Current regulation, 16 CCR § 1719, states that a "recognized school of pharmacy" means a school accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education (ACPE). Touro University currently has pre-candidate statues. **(Attachment B)**

ACTION ITEM 3

That the Board of Pharmacy grant 6 hours of continuing education to pharmacists that complete the Pharmacist Assessment Mechanism (PSAM) administered by the National Association of Boards of Pharmacy (NABP).

Discussion
At the last Licensing Committee meeting, the committee discussed the announcement by NABP regarding the development of the PSAM. The PSAM is an evaluation tool intended to assist pharmacists in obtaining objective, non-punitive feedback on their knowledge base and is available on NABP's web site. **(Attachment C)**

The PSAM is applicable to general pharmacy practitioners in all practice settings. It consists of 100 multiple-choice questions and is divided into three sections of equal length. Each section can be completed in as little as one hour, but a maximum of three hours per section is allowed. Pharmacists may take all three sections in one setting, or complete one section at a time, but once a section is begun it must be completed in its entirety. All three sections must be completed within 30 days of when pharmacists complete the first section. The fee for PSAM is $75.

During the meeting in June, the committee learned that the Idaho State Board of Pharmacy would grant 4 hours of Board-approved CE to pharmacists for completing the PSAM. More recently, Tennessee will grant 3 hours of CE. NABP did pursue accreditation of the PSAM by the Accreditation Council for Pharmacy Education (ACPE), but the accreditation was denied. It was also suggested by the California Pharmacists Association (CPhA) that the Pharmacy Foundation of California approve the PSAM as another CE option for California pharmacists. However, it not clear whether or not CPhA had pursued this suggestion.

NO ACTION

Request from University Compounding Pharmacy to Require Licensure of all Pharmacies that Compound

Pharmacist Joe Grasela representing University Compounding Pharmacy requested that the Licensing Committee consider a requirement that all compounding pharmacies have a special compounding license. He stated that the sterile compounding license has been in place for two years and it has raised the quality of compounded products available to the public. He is suggesting that a special license be required for pharmacies whether they compound injectable sterile products or non-sterile products. **(Attachment D)**

Mr. Grasela explained that this special compounding license for pharmacies is necessary to protect the public. He stated that capsules can do as much harm as injectables. Creams improperly used containing lidocaine can cause cardiac arrest. Oral inhalations, solutions and eye drops can be contaminated. Many other non-compounded non-sterile products can cause harm as an improperly made sterile product.

He also felt that by requiring this special compounding pharmacy license, California would be leading the way and demonstrating to the federal Food and Drug Administration (FDA) that California is regulating compounding pharmacies contrary to FDA's contention that Boards of Pharmacy are not doing enough in this area.

Pharmacist Grasela also stated that by having a special compounding pharmacy license, the board would be creating a new specialty of pharmacy. This new compounding specialty will be similar to nuclear pharmacy, home health care pharmacy, and hospital pharmacy and will provide credibility to the public and provide access to products that cannot be made by manufacturers.

There is concern regarding the compounding of inhalation and ophthalmic drug products. It was noted that both the original legislation and regulation proposals regarding sterile compounding included inhalation and ophthalmic drug products; however, because of the opposition, the legislation and regulations were limited only to compounded sterile injectable drug products.

Last year, the board's Workgroup on Compounding drafted legislation and regulations to govern compounding, which the board approved. While the bill, AB 595, was stalled this year due to opposition from the Department of Health Services (DHS), the board will eventually move forward with the regulations. The committee noted that the regulations are comprehensive and provide regulatory oversight for all compounded drug products, which includes training requirements of all pharmacy personnel who compound and a quality assurance component that guarantees that the compounded drug product meets the specified criteria of strength and quality. It was noted that the workgroup did not discuss whether a special license for all pharmacies that compounded was necessary to protect the public; however, it was the board's position that the

legislative and regulatory proposals were important consumer measures and will continue to pursue them actively.

The committee did not support the request that the board require a special license for all pharmacies that compound drug products and advised Mr. Grasela that the professional association may want to sponsor such legislation, at which time the board would take a position. Any proposal to require a special license would have a fiscal impact on the board and licensees. Pharmacies would have to pay an additional license fee of $500, and the board would be required to add more staff, if the same opening and annual inspection requirements were continued.

Request for Comments on the Definition of Pharmacist's Scope of Practice Consistent with Pharmacy Law for Disaster Response Teams

Since 2005, a group of individuals from various state and local agencies and some private associations have been meeting to design an advance registration system to prescreen and identify medical providers for quick deployment in response to disasters and bioterrorism events.

The group has been meeting under the authority of the state Emergency Medical Services Authority under a Health Resources and Service Administration Hospital Bioterrorism grant. This project is the "Emergency System for Advanced Registration of Volunteer Health Professionals" (ESAR-VHP). The Assistant Executive Officer Virginia Herold has been participating as the board's representative.

One item that has been requested is the scope of practice for pharmacists in emergency situations. Ms. Herold and Supervising Inspector Robert Ratcliff have developed a preliminary scope of practice for which they seek comment and input. **(Attachment E)**

The final version will state in layperson's terms the duties pharmacists can perform under emergency conditions. For example, a draft version of the emergency scope of practice for dentists envisions the ability to suture outside the mouth or set bones in faces.

Request from Accreditation Council for Pharmacy Education (ACPE) for Comments by November 1, 2005 on the Draft PharmD Standards and Guidelines

ACPE is the accreditation agency for all the pharmacy schools in the United States. California will only accept applications from students who have graduated from an ACPE accredited school of pharmacy. ACPE is revising its standards and guidelines and is requesting comments by November 1, 2005. A copy of the revised guidelines can be obtained from their web site: www.acpe-accredit.org.

Development of Proposal to Update the Definition of a Pharmacy, a Nonresident Pharmacy, Pharmacist Practice and Licensure of Out-of-State Pharmacists

Since December 2004, the Licensing Committee has been working to respond to inquiries and comments pertaining to the scope of practice of pharmacy, particularly to the practice of

pharmacy outside of a traditional pharmacy setting, and to the provision of services to California patients by pharmacies, pharmacists, and ancillary staff outside state lines.

The committee agreed to address these issues through its quarterly meetings. However, the committee was encouraged to develop a concrete proposal sooner rather than later in anticipation of the implementation of provisions of the Medicare Modernization Act (MMA) addressing pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act, which are expected to take effect in 2006.

Following an initial overview document prepared for the December 2004 meeting, a draft of proposed statutory changes was prepared for the March 2005 meeting. That draft was the basis for discussions and reactions at the March and June 2005 meetings.

Based on discussions and feedback at the March and June 2005 meetings, liaison counsel with the Attorney General's Office, DAG Joshua Room drafted statutory changes to frame the previous discussions in terms of the various policy choices presented. As always, the primary concern for the board is protection of the California public.

As the committee has defined and discussed them, there are three primary areas in which further specification and possible statutory change has been debated: (1) Given what has been or may be an increase in the number of entities/premises, both within California and outside of California, that are mostly focusing on "prescription review" and/or "cognitive services" separate from and/or in the absence of traditional "pharmacy" tasks such as the actual filling of prescriptions and dispensing of drugs, what can or should the Board do to license those entities/premises, as "pharmacies" or otherwise; (2) When those "review" or "cognitive" services are provided by out-of-state pharmacies or pharmacists to California patients, particularly when out-of-state pharmacists are not located in a licensed premises, should the Board require that: the out-of-state pharmacist have a California license, or an alternative California registration; that the pharmacist at least be affiliated with an entity, i.e., a "pharmacy," that is licensed in California; that out-of-state "pharmacies," however defined, have a PIC licensed in California; and/or should the Board depend on discipline by pharmacists' (and pharmacies') home states of licensure to ensure compliance; (3) In order to conform California law to federal expectations, to permit California licensees to practice fully as professional pharmacists, and/or to maximize the opportunities available under Medicare Part D, should the definitions and scope of practice of pharmacy presently stated in Pharmacy Law be expanded and/or further specified by the Board?

The committee was provided with possible responses that were not intended to be comprehensive. **(Attachment F)**

1. Definition of "Pharmacy"

One of the primary topics of Committee discussion has been, in light of the apparently increased emphasis on provision of professional "cognitive services" (e.g., DUR, MTM) by pharmacists, which may or may not be provided out of a traditional "pharmacy" premises: (a) whether to license facilities, in California or outside of California, from which such services are provided

(which do not otherwise fit the traditional definition of a "pharmacy") *at all*; and (b) if so, whether to license them as "pharmacies," some variant thereof, or as something else entirely.

The draft statutory proposal prepared for the March 2005 meeting assumed that facilities in which "pharmacy" was being practiced (whether "pharmacy" as in prescription-filling, or "pharmacy" as in consultation, MTMP, etc.) would need to be licensed as pharmacies. It identified three separate *types* of pharmacies for licensure: (i) "Intake/dispensing" pharmacies - traditional pharmacies; (ii) "Prescription processing" pharmacies - offering prescription review services for another pharmacy or other provider; and (iii) "Advice/clinical center" pharmacies – providing clinical/cognitive services directly to patients or providers. It also provided for "nonresident pharmacies" that could be any of these three types. The draft assumed that the three (four) types would not be mutually exclusive, i.e., a given facility could overlap. Various statutory options were provided that accomplished the same goal.

There was considerable discussion and opposition to requiring California licensed pharmacists to be licensed as an "Advice/clinical center pharmacy." It was emphasized that the board needs to recognize the independent practice of pharmacists and this proposal doesn't. The public is adequately protected by the pharmacist licensure.

It was also questioned why the board requires an entity that processes prescriptions to be licensed as a pharmacy. It was explained that the processing of prescriptions under current pharmacy law constitutes the practice of pharmacy and therefore, must be practiced in a licensed pharmacy. It is the location that would receive telephonic and electronic orders for prescriptions and maintain the prescription and patient information, directing the prescription to a particular pharmacy for filling and dispensing. While the pharmacy law authorizes a pharmacist to electronically enter a prescription or order into a pharmacy's or hospital's computer, the law doesn't allow other pharmacy personnel to process prescriptions under the supervision of a pharmacist. To allow such a practice outside a pharmacy would require explicit language. An option may be to allow the practice pursuant to a contract with a pharmacy as long as the original prescriptions records and record of the pharmacist's review be maintained by the filling pharmacy.

Another option provided was to license the facilities but not call them "pharmacies." Other options included (i) licensing such entities as "pharmacies" under the current definition(s), without revision, (ii) not licensing these entities at all, (iii) deferring the licensure of these entities to some other agency (e.g., Department of Health Services), or (iv) awaiting some consensus at the national level about interstate cooperation thereon. None of these alternatives would require statutory revisions.

2. Out-of-State Pharmacists (and Pharmacies)

A second primary topic for discussion has been whether and/or how to regulate those out-of-state pharmacists who provide cognitive services and/or prescription processing services to and/or for California patients and providers, particularly where those pharmacists are doing so not through affiliation with or employment by a licensed entity (e.g., nonresident pharmacy, advice center, or

prescription processing center), but on a consulting or other non-site-specific basis. During all of the Committee's discussion(s) of this issue, there has been acknowledgment of a need to balance the Board's primary duty to protect the public with its desire not to impede either patient access to services (particularly for California patients) or to squeeze pharmacists out of the marketplace.

This issue has not arisen directly in the past, with regard to out-of-state pharmacists filling and/or dispensing prescription drugs, because until now those out-of-state pharmacists have worked in (or at least this has been the assumption) nonresident pharmacies that were themselves required to maintain licensure. So there has not previously been a perceived need to consider licensing out-of-state pharmacists separately (in California) from the entities in which they practice. Now, however, there apparently has been or may be an industry growth in the number of pharmacists in other states providing services to California patients or providers who are not permanently or indivisibly affiliated with any particular (licensed) premises. This seems particularly likely with regard to cognitive/prescription processing services, which due to imaging/file-sharing advances, are not nearly as tied to a particular "place" as are (or were) dispensing functions.

Secondary and tertiary considerations arise from this discussion as well, including: whether to limit the requirement of California licensure to out-of-state pharmacists providing cognitive or prescription processing services, or to extend it to those dispensing medications as well; whether to require this licensure of all pharmacists providing such services to California patients and/or providers, or only those not affiliated with a licensed entity of some kind; whether to put primary responsibility for record-keeping pertaining to provision of services to California patients on the shoulders of a licensed entity, or on the shoulders of the pharmacist (whether or not licensed in California); and/or if out-of-state pharmacists are not required to be licensed in California, how best to enforce violations of (particularly, California) law committed by those pharmacists.

The wide-ranging discussion at the March and June 2005 meetings has seemed to acknowledge a possibility of choosing between (this list is not exhaustive or exclusive, only reflective of those options primarily discussed) (a) licensing all out-of-state pharmacists, (b) requiring out-of-state pharmacists to maintain some form of registration short of licensure, (c) licensing only entities under the auspices of which out-of-state pharmacists would (be required to) practice, and/or (d) requiring that the pharmacists-in-charge of these licensed entities also be licensed in California.

The March 2005 draft statutory chose a combination of (a), (c), and (d), requiring licensure for all out-of-state pharmacists providing cognitive services or prescription processing services to California, and *also* requiring licensure of the pharmacist-in-charge of a nonresident pharmacy.

Concern was expressed at the March and June 2005 meetings that this requirement of licensure would be burdensome to nonresident pharmacies and out-of-state pharmacists. Various other options were discussed at the meetings such as a "registration program" for the nonresident pharmacist, some type of national license certification by the National Association of Boards of Pharmacy (NABP), reciprocity, and/or no additional licensure but a requirement that the out-of-state pharmacist meet California practice standards. Another possibility would be striking the requirement that the individual practitioner be licensed in California, instead requiring that the out-of-state pharmacist providing services (or drugs) to California patients practice under the

auspices of an entity licensed as a nonresident pharmacy (or other form of site license), with a possible further requirement that the pharmacist-in-charge be a California licensee.

As was discussed at the June 2005 Committee meeting, NABP model rules would require that a pharmacist providing telepharmacy services across state lines identify himself or herself to any patient as a "licensed pharmacist," notify patients of the jurisdiction in which he/she is currently licensed to practice pharmacy, and register (with relevant state boards) to practice telepharmacy across state lines and provide patients with the jurisdiction's Board address and phone number.

Among the above-listed alternatives to requiring licensure of all out-of-state pharmacists (or at least out-of-state PICs) that have been discussed, two were presented as possible statutory form: (1) the possibility of a non-licensure "certification" of some sort (perhaps supported by NABP), which would require conformance to California standards; and (2) the possibility that licensure would not be required of out-of-state pharmacists so long as services delivered to any California patient were delivered under the auspices of a California-licensed pharmacy/entity.

The California Pharmacists Association (CPhA) provided a similar proposal that would require an out-of-state pharmacist providing cognitive pharmacy services to register as a nonresident provider of pharmacy services. **(Attachment G)**

The third and final primary topic for discussion has been whether and/or how to amend or expand statutory definition(s) of practice as a pharmacist to (i) better conform to existing practice, (ii) emphasize the professional development of pharmacy, and/or (iii) maximize the potential for California pharmacist practice reimbursement under Medicare Part D.

The statutory proposals pertaining to this subject area made along with the others for the March 2005 Licensing Committee meeting have not generated comment on specifics of the proposed language so much as they have inspired discussion about whether (and how) it is a good idea to expand and/or specify the practice definitions in this way. Therefore, the committee was provided with a verbatim reiteration of those statutory amendments pertaining to this subject that were presented in March 2005. Except as already specified above, at least some of these (particularly revisions to B&P 4052, which essentially just reduce the size of section 4052 and relocate subparts to sections 4052.1-4052.3) seem non-controversial. Others have not yet been fully debated.

In brief, the idea behind many of these suggested amendments/revisions is to recognize in statute that the practice of pharmacy means far more than simply counting and dispensing medications, that it is a professional practice, and that it can be practiced both within and without the four walls of a traditional pharmacy, by licensed professional pharmacists.

The committee discussed this final section and there was support for these changes and updates to pharmacy law. It was suggested that this section be separated from the first two sections of the proposal and be pursued legislatively.

The committee will continue the discussion on this proposal at its December meeting.

Meeting Summary of September 21, 2005 (Attachment H)

Licensing Statistics (Attachment I)

Competency Committee Report (Attachment J)

Quarterly Status Report on Committee Goals for 2005/06 (Attachment K)

ATTACHMENT A

Article 7.5 – Injectable Sterile Drug Products

4127. The board shall adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy.

4127.1. (a) A pharmacy shall not compound injectable sterile drug products in this state unless the pharmacy has obtained a license from the board pursuant to this section. The license shall be renewed annually and is not transferable.
(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the pharmacy license at that location. A license to compound injectable sterile drug products may not be issued until the location is inspected by the board and found in compliance with this article and regulations adopted by the board.
(c) A license to compound injectable sterile drug products may not be renewed until the location has been inspected by the board and found to be in compliance with this article and regulations adopted by the board.
(d) Pharmacies operated by entities that are licensed by either the board or the State Department of Health Services and that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.
(e) The reconstitution of a sterile powder shall not require a license pursuant to this section if both of the following are met:
(1) The sterile powder was obtained from a manufacturer.
(2) The drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection pursuant to this division.
(f) This section shall become effective on the earlier of July 1, 2003, or the effective date of regulations adopted by the board pursuant to Section 4127.
(g) The board may, at its discretion, issue a temporary license to compound injectable sterile drug products, when the ownership of a pharmacy that is licensed to compound injectable sterile drug products is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary license fee shall be established by the board at an amount not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary license nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

ATTACHMENT B

Touro University
California
EDUCATING CARING PROFESSIONALS TO SERVE, TO LEAD, TO TEACH
1310 Johnson Lane . Mare Island, Vallejo, CA 94592 . (707) 638-5200 . Fax (707) 638-5255 . www.tu.edu

August 22, 2005

Patricia Harris, Executive Officer
Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

Dear Ms. Harris:

Touro University College of Pharmacy requests that the Board of Pharmacy process the pharmacist intern applications of our 64 students in the Class of 2009 in time for curricular activities planned for late October 2005. We support this request with the following information.

Touro University College of Pharmacy opened its doors to students in August 2005. The College currently has pre-candidate status with the Accreditation Council for Pharmacy Education (ACPE). Touro will be reviewed by ACPE for advancement to candidate status during the 2005-2006 academic year. As you well know, accreditation is based on adherence to ACPE Standards. Our review, scheduled for Spring 2006, will be based upon the new standards that ACPE has been developing and reviewing with the help of the educational community and the profession and which will be voted upon in January 2006. At present, schools and colleges of pharmacy who will be reviewed are using the Draft Revision of ACPE Standards 2000 and Proposed Guidelines as their tools in preparation for ACPE review.

The ACPE Draft Standards specify 300 hours of Introductory Pharmacy Practice Experience or IPPE during the pre-rotational portion of the curriculum. For our program, this equates to 75 hours per semester during the first two years. Our clinical partners expect that students enrolled in IPPEs will be licensed pharmacist interns. Therefore, the licensure process is important in meeting ACPE guidelines for accreditation. This is the basis for our request that our students be licensed in time for IPPE activities in the Fall 2005 semester.

Dr. Debbie Sasaki-Hill, Associate Dean for Clinical Affairs (707.638.5906) or I (707.638.5221) look forward to answering any questions you might have and assisting in any way in moving this request forward. The completed applications of the Class of 2009 were sent under separate cover last week. We send our thanks in advance to you and your staff for your assistance in this matter.

Sincerely,

Katherine Knapp

Katherine K. Knapp, Dean

Note:

Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

Article 3. Pharmacist Candidates

§1719. Recognized Schools of Pharmacy.

As used in this division, "recognized school of pharmacy" means a school of pharmacy accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education or otherwise recognized by the board.

Note:

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4200 of the Business and Professions Code.

§1720. Application for Pharmacist Examination and Licensure.

(a) An application for examination shall be submitted on the form provided by the board, and filed with the board at its office in Sacramento.
(b) The fee required by subdivision (d) of section 1749 of this Division shall be paid for each application for initial examination and for any application to retake the examination described in section 4200.2 of the Business and Professions Code. The fee is nonrefundable.
(c)Each applicant shall be solely responsible for applying to and complying with the requirements imposed by the administrators of the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California for the administration of those examinations.

Note:

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4200 and 4200.2, Business and Professions Code.

§1720.1. Graduates of Foreign Pharmacy Schools.

Graduates of foreign pharmacy schools who have been certified by the Foreign Pharmacy Graduate Equivalency Committee shall be deemed by the board to have satisfied the requirements of paragraphs (3) and (4) of Business and Professions Code Section 4200(a). Candidates who have been certified by the Foreign Pharmacy Graduate Equivalency Committee before January 1, 1998, must also provide the board with a score on the Test of Spoken English of least 50. For candidates who took the Test of Spoken English before June 30, 1995, a score of at least 220 must be achieved.

Note:

ATTACHMENT C

National Association of Boards of Pharmacy
1600 Feehanville Drive • Mount Prospect, IL 60056 Tel: 847/391-4406 Fax: 847/391-4502
e-mail
Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary

NABP Launches PSAM, Non-Punitive, Knowledge Evaluation Tool for Pharmacists

5/2/05

NABP Launches PSAM, Non-Punitive, Knowledge Evaluation Tool for Pharmacists

The National Association of Boards of Pharmacy® (NABP®) is pleased to announce that the Pharmacist Self-Assessment Mechanism™ (PSAM™) is now available. The PSAM is an evaluation tool intended to assist pharmacists in obtaining objective, non-punitive feedback on their knowledge base and is available on the Association's Web site at www.nabp.net.

"Today's escalating complexities of health care delivery systems and the evolving role of the pharmacist as the patients' medication expert make it increasingly important for pharmacists to participate in a formal lifelong learning program," explains NABP President Donna M. Horn. "The PSAM will greatly aid pharmacists as they endeavor to better serve their patients because it provides objective feedback on their knowledge base – an outcome that is often difficult for pharmacists attempting to evaluate themselves."

The PSAM, which is applicable to general pharmacy practitioners in all practice settings, consists of 100 multiple choice questions and is divided into three sections of equal length. Each section can be completed in as little as one hour, but a maximum of three hours per section is allowed. Pharmacists may take all three sections in one sitting, or complete one section at a time, but once a section is begun it must be completed in its entirety. All three sections must be completed within 30 days of when pharmacists begin the first section. The fee for the PSAM is $75.

To benefit pharmacists and serve as a learning tool, the end of each section offers a feedback loop, which displays each question, the answer selected, the correct answer, a brief rationale, and a reference where more information relating to the topic may be obtained. Upon completion of the PSAM, pharmacists receive a Record of Completion indicating their name and date of completion.

As a non-punitive learning tool, the PSAM does not report scores to any person or group other than the pharmacist utilizing the PSAM. Once they have completed the mechanism, pharmacists will receive a confidential Achievement Report indicating the percentage of questions answered correctly in each of the five content areas as well as the overall percentage of questions answered correctly. The Achievement Report is separate from the Record of Completion and has no identifiers of the test taker.

The PSAM is one part of NABP's Continuing Professional Development (CPD) program, a cyclical process that includes five components: reflecting upon one's practice, conducting a learning needs assessment, developing a learning plan, implementing the learning plan, and evaluating the learning plan outcomes. As a component of CPD, the PSAM facilitates the general pharmacy practitioner's ability to conduct a needs assessment and develop a learning plan.

For more information about the PSAM, contact NABP's Customer Service Department at 847/391-4406 or via e-mail at custserv@nabp.net, or visit the Association's Web site at www.nabp.net.

If you have any questions or comments, please e-mail **custserv@nabp.net**.

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June 2005

Idaho Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

3380 Americana Terr, Suite 320, Boise, ID 83706

Marilyn Silcock, PharmD

Marilyn is now completing her second and final five-year term as a member of the Idaho Board of Pharmacy. Marilyn has been a very active and dedicated Board member. She has served as chairman twice during her 10 years on the Board and never missed a meeting during that time. We have been very fortunate in having Board members like Marilyn give of their time and energy to serve the people of Idaho.

The Board consists of five members, four pharmacists and one public member. Although it is not required by law, we have been able to maintain Board members representing independent, chain, and health system pharmacists. Marilyn is the director of pharmacy at Portneuf Medical Center in Pocatello, ID, and represents health system pharmacists. The Idaho State Pharmacy Association submits the names of qualified candidates to Governor Dirk Kempthorne for his consideration in appointing new Board members.

Board-approved Continuing Education – New Program: PSAM

One of the critical issues in pharmacy is continuing professional development (CPD); that is, the means by which pharmacists maintain, improve, and broaden their knowledge and skills. The Idaho Legislature has found and declared that because of the continuous introduction of new therapeutic and diagnostic agents and the changing concepts in the delivery of health care services in the practice of pharmacy, it is essential that a pharmacist undertake a continuing education (CE) program in order to maintain his or her professional competency and improve his or her professional skills.

Since 1980 the Idaho Board of Pharmacy has required that no annual renewal license shall be issued to a pharmacist until such pharmacist shall have submitted proof to the Board that he or she has satisfactorily completed an accredited program of continuing professional education during the previous year to help assure continued competence to engage in the practice of pharmacy. Idaho's requirements recognize CE programs offered by CE providers approved by the Accreditation Council for Pharmacy Education (ACPE), Continuing Medical Education, and Board-approved programs.

The Idaho Board has approved the Pharmacist Self-Assessment Mechanism™ (PSAM™) offered by the National Association of Boards of Pharmacy® (NABP®) as a Board-approved program that will satisfy four (4) hours of Board-approved CE. The PSAM is an evaluation tool that will assist pharmacists in obtaining objective, non-punitive feedback on their individual knowledge of current practice therapies. The assessment tool is applicable to general pharmacy practice and all practitioners. It consists of 100 multiple-choice questions and is divided into three sections of equal length. Each section can be completed in less than one hour; however, a maximum of three hours per section is allowed. A pharmacist may take all three sections in one sitting, or complete one section at a time. However, once a section is begun it must be completed in its entirety. Once the PSAM is begun all sections must be completed in three weeks. The fee for the PSAM is $75.

Questions in the PSAM are based on patient profiles and simulate real-life practice situations and patient therapies. Because the PSAM is an assessment and learning tool, the pharmacist is provided with feedback on each question. The feedback information displays each question, the answer selected, the correct answer, a brief rationale for the correct answer, and a reference where more information about the answer or applicable treatment guidelines can be obtained.

Upon completion of the PSAM, pharmacists will receive a Record of Completion indicating their name and the date of completion. The PSAM will report the assessment evaluation score directly to the pharmacist in a separate report and will not report individual identified scores to the Board, NABP, or any other person, group, or entity unless so authorized by the pharmacist. The confidential Achievement Report forwarded directly to the pharmacist will indicate the percentage of questions answered correctly in each of the primary content areas as well as the overall percentage of questions answered correctly.

You will only need a copy of your Record of Completion to satisfy the four hours of Idaho Board-approved CE. The Board will not request the report of your assessment evaluation score.

The PSAM is one part of the much larger CPD program that NABP is fashioning with other state and national pharmacy organizations. The CPD program that is being advocated by NABP and other pharmacy associations includes five components: reflection upon one's practice, conducting a self-assessment, developing a learning plan, implementing the learning plan, and evaluating the outcomes of the learning plan. The PSAM facilitates components one and two of the CPD strategy. After completing the PSAM, pharmacists will be able to select continuing programs that address the results of the self-assessment and are beneficial to the pharmacist's particular practice setting. NABP is working with the Board and ACPE to ensure that quality CE programs are available in areas identified by the PSAM to assist pharmacists in developing individual CE program learning plans and completing meaningful CE programs.

For more information about the PSAM, visit www.nabp.net or contact NABP at 847/391-4406 or via e-mail at custserv@nabp.net.

ATTACHMENT D

University Compounding Pharmacy

1875 3rd Avenue
San Diego, CA 92101
PH# 619-683-2005

07/20/2005

Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814,

Dear Patricia Harris, Executive Officer,

As a topic to discuss at a future board meeting I would like to bring up licensure for compounded non-sterile products be covered under one compounding license, along with sterile products, to be known as the "Prescription Drug Compounding License".

Now that the sterile compounding license has been in effect for over 2 years, I feel that it has raised the standard in quality-compounded products available to the public. As we all know, the reason why we instituted this license is to protect the public from poor quality compounded sterile products that can cause harm. Because of our vast experience in compounding prescription medications we feel that the non-sterile compounded products can also cause harm to the public. We feel that all compounds should be covered by the "Prescription Drug Compounding License" for the following reasons:

First, to protect the public. Capsules can do as much harm as injectables. Creams improperly used containing lidocaine can cause cardiac arrest. Oral inhalations, solutions and eye drops can be contaminated. Many other compounded non-sterile products can cause harm as an improperly made sterile product. By placing these under the one compounding license this will keep the public safer. We will help keep the unqualified pharmacist, that is not seriously interested in compounding, out of the compounding field.

Second, the FDA is stating that the Boards of Pharmacy in the USA is not doing enough to regulate compounding pharmacies. California Board is leading the way. By placing both compounding products for sterile and non-sterile drugs covered by ONE special license we will set a template for the rest of the USA Boards of Pharmacy and help satisfy the FDA.

Third, by just having this form of license to compound prescription drugs we will have created a brand **NEW SPECIALTY OF PHARMACY**. This new **COMPOUNDING SPECIALTY** will be similar to nuclear pharmacy, home health care pharmacy, hospital pharmacy and provide it with credibility so that the public will have confidence and access to products that cannot be made by manufacturers. New generations of pharmacists will have an opportunity to practice the art of compounding with the support of the Board of Pharmacy in this great new specialty that has always been the corner stone of pharmacy.

Lastly, California Board of Pharmacy will be leading the way to set an example for the other states to follow. As we all know compounded prescriptions is the reason why we have the profession of pharmacy and this licensure we will help keep that credibility in compounding with California leading the way.

If I can be of any help in this project, please let me know. I can be contacted at (858) 483-4715.

Sincerely,

Joe Grasela
Compounding Pharmacist

ATTACHMENT E

Pharmacist Scope of Practice:

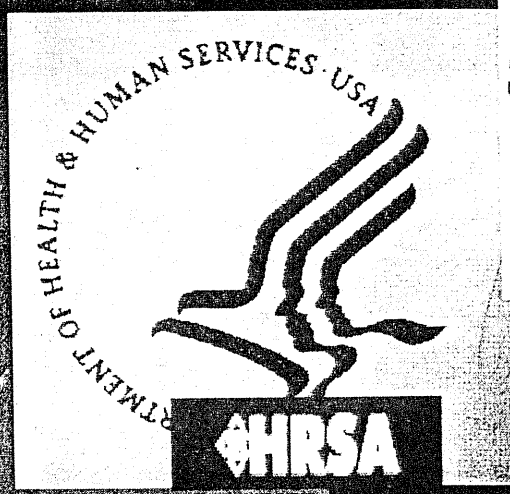
1. Prepare and dispense prescription medication and devices
2. Counsel patients and health care providers about medication and medication therapy
3. Know dosing and strengths of medication
4. Identify medication (by name and strength)
5. Recommend over-the-counter medication
6. Identify generically equivalent medication
7. Identify therapeutically equivalent medication
8. Identify adverse reactions from medication and the combined effects of multiple drugs
9. Perform drug therapy reviews and management of patients' drug therapy
10. Initiate, adjust or implement patient drug therapy
11. Interpret and verify orders for prescription medication
12. Ensure appropriate drug storage, documentation, labeling and record-keeping
13. Maintain accurate patient profiles and records
14. Supervise pharmacy technicians, pharmacist interns and ancillary personnel in the pharmacy
15. Compound specialty medication pursuant to prescription orders or for prescriber office use
16. Collaborate with health care providers regarding patient care
17. Administer or furnish drugs or vaccinations
18. Recommend appropriate drug products or therapy or refer patients for medical care

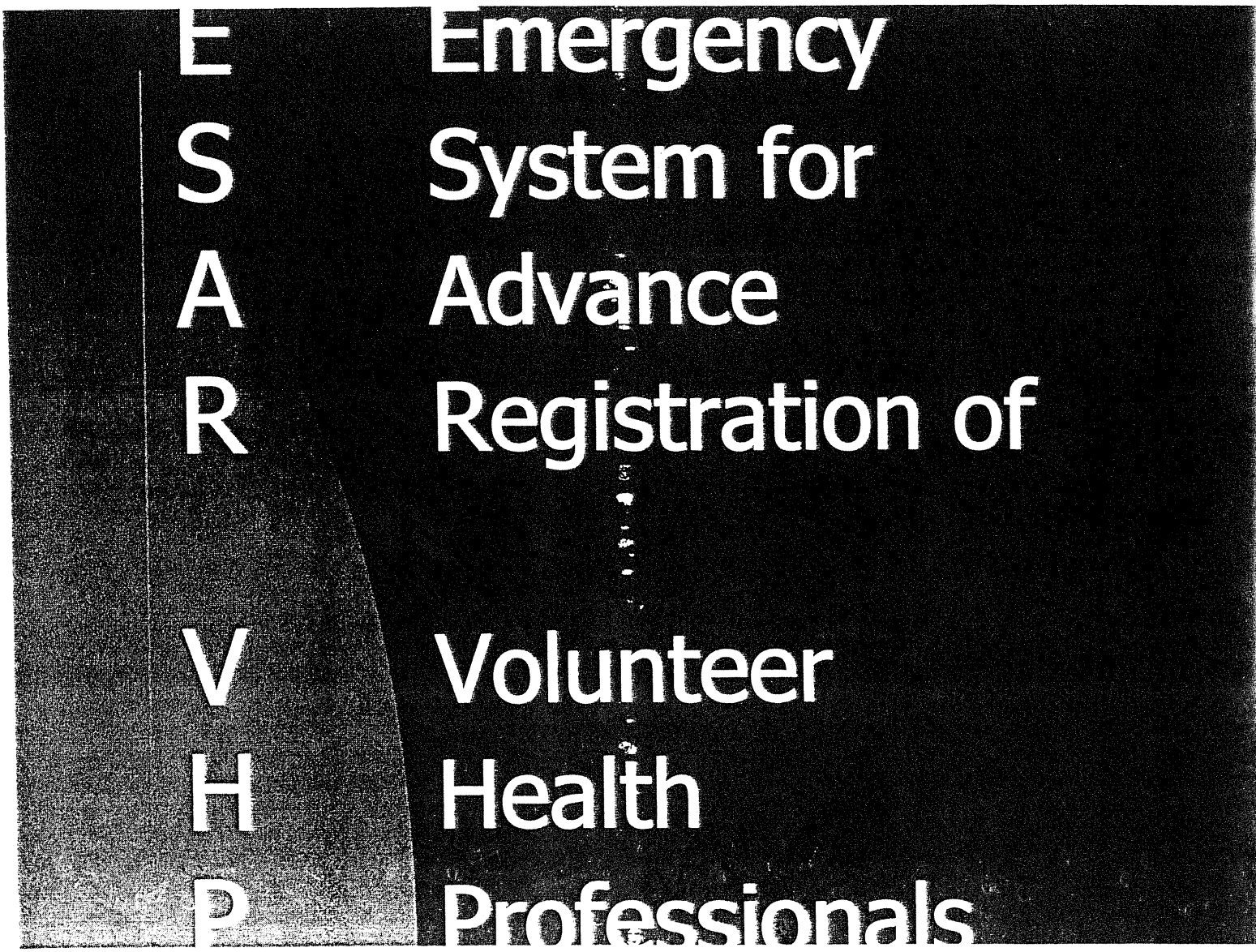
Recommended Scope of Practice in Emergency Response:

Pharmacists with virtually no additional training can:

1. Identify, organize and sort medication by drug class at mass distribution points or treatment centers
2. Provide first aid, CPR (if certified) and basic life support (if certified).
3. Take medical histories,
4. Take vital signs
5. Draw body fluids
6. Roll-out the national stockpile of drugs (training may be required).

The California ESAR-VHP




E
S
A
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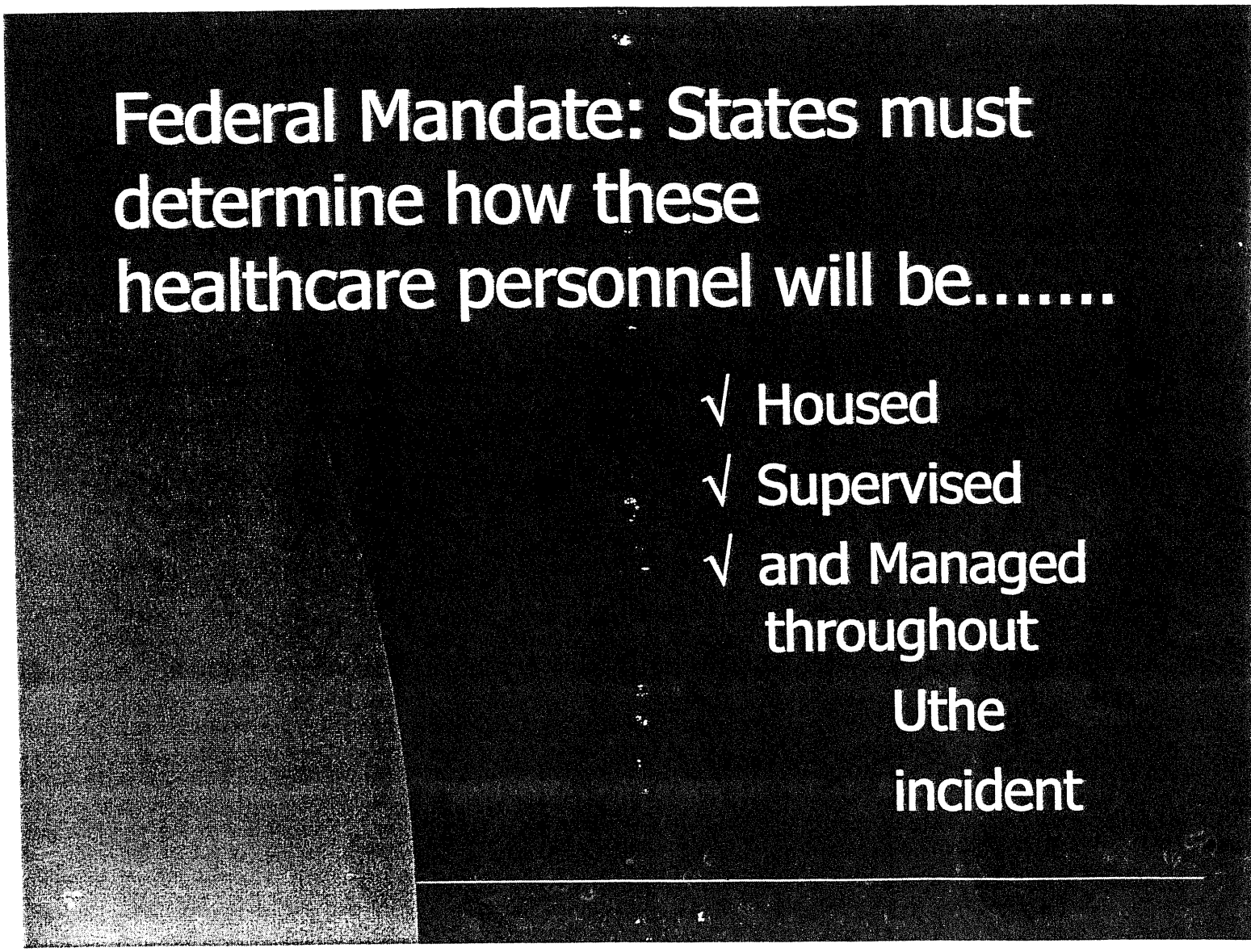
P
Emergency
System for
Advance
Registration of
Volunteer
Health
Professionals

Federal Government Mandate

States must develop a system
that provides for
the advanced registration & credentialing
of clinicians
in order to augment a hospital
or other medical facility
and thereby meet
the increased patient/victim care needs
during a declared emergency

The idea behind the ESAR-VHP is to register and credential the historically large stream of healthcare personnel that wish to volunteer their expertise during a disaster

PRIOR



Recruited
Processed
Credentialed
Integrated
Insured
Trained

First Wave Focus:

- Physicians
- Registered Nurses
- Nurse Practitioners
- Dentists
- Pharmacists
- Paramedics
- Respiratory Care Practitioners
- Behavioral Health Providers

CA ESAR-VHP Mission

California ESAR-VHP is a statewide system,
which operates in coordination
with County Operational Areas*,
to recruit, register, credential, track, identify, deploy,
& maintain
currently licensed volunteer healthcare professionals
for response to emergencies, disasters
& terrorist incidents
in California & throughout the nation.

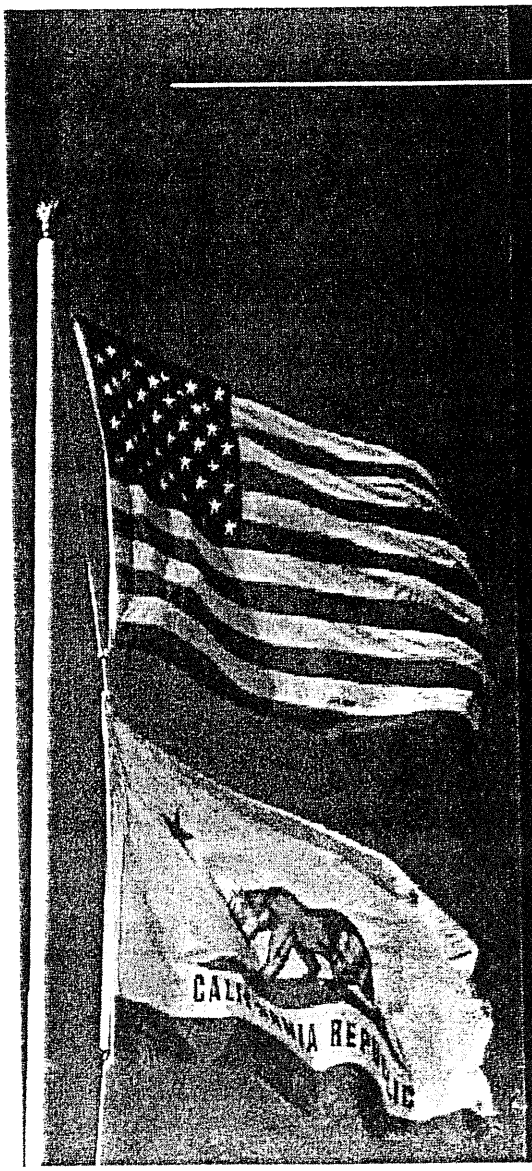
*Operational Area (OA)

In California, an Operational Area is defined as the governing body of each county plus all the political subdivisions located within that county.

Examples:

- Municipal & County Government
- Public Health Departments
- Emergency Management Agencies
- Hospital Districts
- Other Special Districts (e.g. utility, fire, law, police, etc.)

~~California ESAR-VHP~~



will be

state-based

and state-wide but

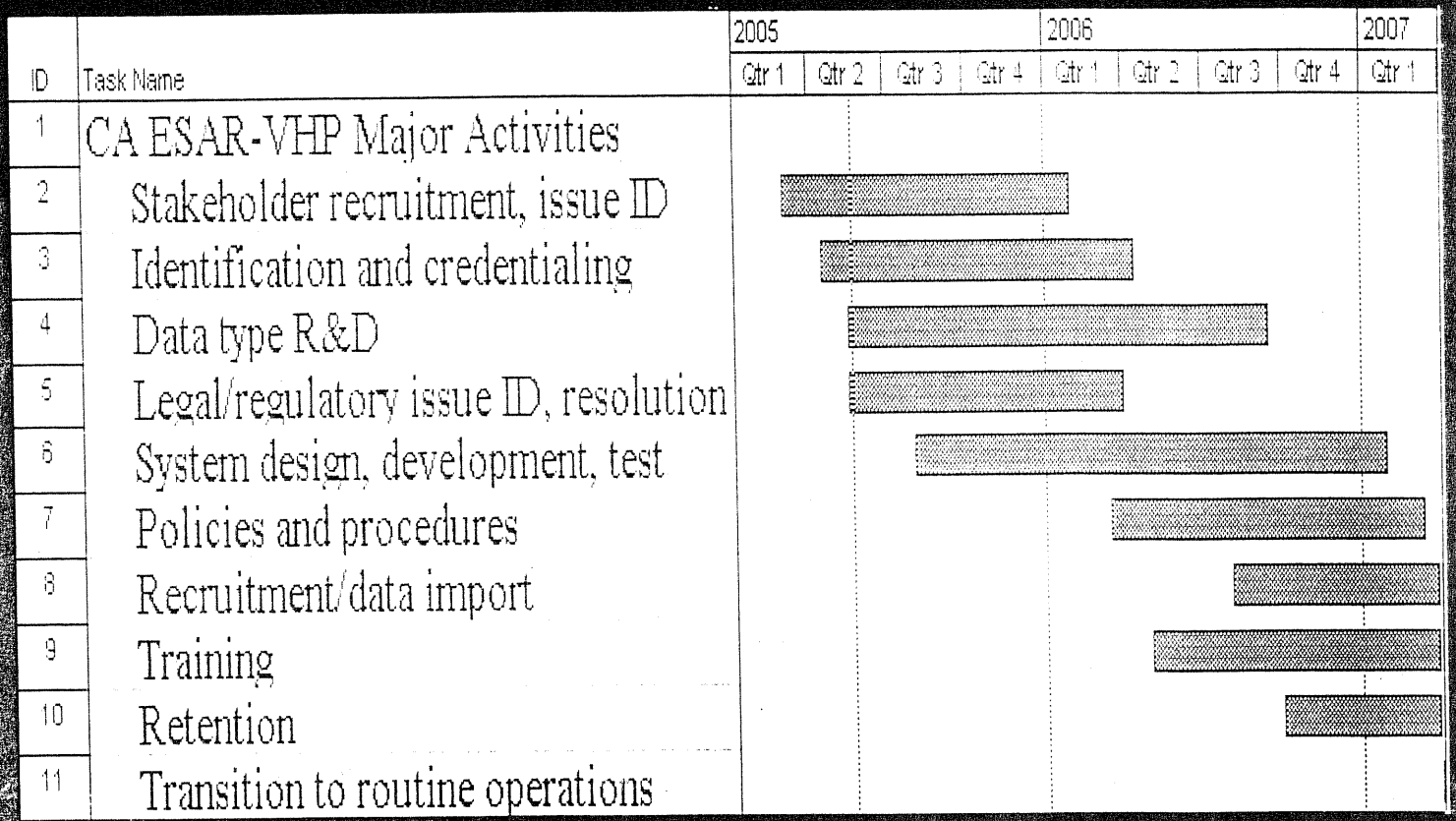
with national

interoperability

CA ESAR-VHP Committee Representation

- State & County Agencies, Licensing Boards
- Professional Associations
- EMS Agencies & Associations
- Major Healthcare Providers & Associations
- Volunteer Organizations
- Professional Legal Consultants (soon)
- State Insurance Commission Rep (recruiting)
- Information Technology Experts (recruiting)
- Labor Union Reps (recruiting)

CA ESAR-VHP Major Activities



Some of the Issues to be Addressed

- Volunteer Liability & Malpractice Protection
- System Sustainability Post-grant
- Regulatory Impediments
- Volunteer Job Release & Job Protections
- System Access Authority
- Data System / Security / HIPAA Compliance
- Local Emergency System Integration

ATTACHMENT F

State of California Department of Consumer Affairs

Memorandum

To: Licensing Committee Date: September 12, 2005

From: Patricia F. Harris
Executive Officer

Subject: **Development of Proposal to Update the Definition and Requirements for Pharmacy, Nonresident Pharmacy, Pharmacist Practice and Licensure of Out-of-State Pharmacists**

Since December 2004, the Licensing Committee has been working to respond to inquiries and comments pertaining to the scope of practice of pharmacy, particularly to the practice of pharmacy outside of a traditional pharmacy setting, and to the provision of services to California patients by pharmacies, pharmacists, and ancillary staff outside state lines.

The Committee agreed to address these issues through its quarterly meetings. However, the Committee was encouraged to develop a concrete proposal sooner rather than later in anticipation of the implementation of provisions of the Medicare Modernization Act (MMA) addressing pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act, which are expected to take effect in 2006.

Following an initial overview document prepared for the December 2004 meeting, a draft of proposed statutory changes was prepared for the March 2005 meeting. That draft was the basis for discussions and reactions at the March and June 2005 meetings.

Based on discussions and feedback at the March and June 2005 meetings, it seemed most appropriate to take a step back, and to frame the discussion in terms of the various policy choices presented. In recognition of the time-sensitive nature of the Committee's mission to better define these issues prior to implementation of Medicare Part D, however, what follows also contains draft statutory changes to implement the various policy choices. As always, the primary concern for the Board is protection of the California public.

As the Committee has defined and discussed them, there are three primary areas in which further specification and possible statutory change has been debated: (1) Given what has been or may be an increase in the number of entities/premises, both within California and outside of California, that are mostly focusing on "prescription review" and/or "cognitive services" separate from and/or in the absence of traditional "pharmacy" tasks such as the actual filling of prescriptions and dispensing of drugs, what can or should the Board do to license those

entities/premises, as "pharmacies" or otherwise; (2) When those "review" or "cognitive" services are provided by out-of-state pharmacies or pharmacists to California patients, particularly when out-of-state pharmacists are not located in a licensed premises, should the Board require that: the out-of-state pharmacist have a California license, or an alternative California registration; that the pharmacist at least be affiliated with an entity, i.e., a "pharmacy," that is licensed in California; that out-of-state "pharmacies," however defined, have a PIC licensed in California; and/or should the Board depend on discipline by pharmacists' (and pharmacies') home states of licensure to ensure compliance; (3) In order to conform California law to federal expectations, to permit California licensees to practice fully as professional pharmacists, and/or to maximize the opportunities available under Medicare Part D, should the definitions and scope of practice of pharmacy presently stated in Pharmacy Law be expanded and/or further specified by the Board?

What follows are possible responses. These are not intended to be comprehensive.

1. Definition of "Pharmacy"

One of the primary topics of Committee discussion has been, in light of the apparently increased emphasis on provision of professional "cognitive services" (e.g., DUR, MTM) by pharmacists, which may or may not be provided out of a traditional "pharmacy" premises: (a) whether to license facilities, in California or outside of California, from which such services are provided (which do not otherwise fit the traditional definition of a "pharmacy") *at all*; and (b) if so, whether to license them as "pharmacies," some variant thereof, or as something else entirely.

The draft statutory proposal prepared for the March 2005 meeting assumed that facilities in which "pharmacy" was being practiced (whether "pharmacy" as in prescription-filling, or "pharmacy" as in consultation, MTMP, etc.) would need to be licensed as pharmacies. It identified three separate *types* of pharmacies for licensure: (i) "Intake/dispensing" pharmacies - traditional pharmacies; (ii) "Prescription processing" pharmacies - offering prescription review services for another pharmacy or other provider; and (iii) "Advice/clinical center" pharmacies – providing clinical/cognitive services directly to patients or providers. It also provided for "nonresident pharmacies" that could be any of these three types. The draft assumed that the three (four) types would not be mutually exclusive, i.e., a given facility could overlap.

The draft proposal accomplished this expansion in licensure by amending B&P 4037, and by making small related changes to B&P 4120, 4125, 4201, and 4207:

§ 4037. Pharmacy

(a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced ~~and where prescriptions are compounded~~. The profession of pharmacy may be practiced in diverse settings, including the following:

(1) "Intake/dispensing pharmacy" means an area, place, or premises licensed by the board in which ~~"Pharmacy" includes, but is not limited to, any area, place, or premises described in a license issued by the board wherein~~ controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and

from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail by personnel licensed by the board.

(2) "Prescription processing pharmacy" means an area, place, or premises licensed by the board in which personnel licensed by the board engage in and/or supervise drug order/prescription review by performing functions including, but not limited to, data entry, drug utilization review, patient and/or prescriber contact, claims submission and processing, patient profile review, and allergy and drug-interaction review, but in which controlled substances, dangerous drugs, or dangerous devices are not stored, possessed, prepared, manufactured, derived, compounded, nor repackaged, and from which controlled substances, dangerous drugs, or dangerous devices are not furnished, sold, or dispensed at retail.

(3) "Advice/clinical center pharmacy" means an area, place, or premises licensed by the board in which personnel licensed by the board provide cognitive pharmacy services including, but not limited to, clinical advice or information, telephonic or in-person patient consultation, drug utilization review, and medication therapy management, but in which controlled substances, dangerous drugs, or dangerous devices are not stored, possessed, prepared, manufactured, derived, compounded, nor repackaged, and from which controlled substances, dangerous drugs, or dangerous devices are not furnished, sold, or dispensed at retail.

(4) "Nonresident pharmacy" means an area, place, or premises licensed by the board that is located outside this state, that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state, and/or that performs prescription review, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state. It may be any or all of types (a)(1) to (a)(3).

(b) These pharmacy types are not mutually exclusive.

(c) Unless otherwise specified, whenever the term "pharmacy" is used in this chapter, it shall be deemed to refer to every one of the types in (a)(1) to (a)(4). Unless otherwise specified, each requirement made applicable to any pharmacy by this chapter is applicable to all.

~~(b)~~(d) "Pharmacy" shall not include any area in a facility licensed by the State Department of Health Services where floor supplies, ward supplies, operating room supplies, or emergency room supplies of dangerous drugs or dangerous devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility.

(e) "Pharmacy" shall not include any of those clinics listed in Section 4180 or Section 4190.

§ 4120. Nonresident pharmacies; registration; application forms; legislative intent

(a) A nonresident pharmacy shall not sell or distribute dangerous drugs or dangerous devices in this state through any person or media other than a wholesaler who has obtained a license pursuant to this chapter or through a selling or distribution outlet that is licensed as a wholesaler pursuant to this chapter without registering as a nonresident pharmacy.

(b) Applications for a nonresident pharmacy registration shall be made on a form furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of this section.

(c) Each application to conduct a nonresident pharmacy shall specify the type or types of pharmacy for which the application is submitted, pursuant to Section 4037.
(ed) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any nonresident pharmacy.

(de) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to serve as any evidence that the nonresident pharmacy is doing business within this state.

§ 4125. Quality assurance program

(a) Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors and/or inappropriate provision of cognitive services such as prescription review, consultation, drug utilization review, or medication therapy management attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications, or providing cognitive services, so that the pharmacy may take appropriate action to prevent a recurrence.

(b) Records generated for and maintained as a component of a pharmacy's ongoing quality assurance program shall be considered peer review documents and not subject to discovery in any arbitration, civil, or other proceeding, except as provided hereafter. That privilege shall not prevent review of a pharmacy's quality assurance program and records maintained as part of that system by the board as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the pharmacy. Nothing in this section shall be construed to prohibit a patient from accessing his or her own prescription records. Nothing in this section shall affect the discoverability of any records not solely generated for and maintained as a component of a pharmacy's ongoing quality assurance program.

~~(c) This section shall become operative on January 1, 2002.~~

§ 4201. Contents of applications; fees; powers of license holders

(a) Each application to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer, shall be made on a form furnished by the board, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein.

(b) Each application to conduct a pharmacy shall specify the type or types of pharmacy for which the application is submitted, pursuant to Section 4037.

(~~b~~c) As used in this section, and subject to subdivision (~~c~~d), the term "person beneficially interested" means and includes:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that no natural person shall be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

(~~c~~d) In any case where the applicant is a partnership or other unincorporated association, is a limited liability company, or is a corporation, and where the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (a) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

(~~d~~e) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.

(~~e~~f) Upon the approval of the application by the board and payment of the fee required by this chapter for each pharmacy, wholesaler, or veterinary food-animal drug retailer, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer, if all of the provisions of this chapter have been complied with.

(~~f~~g) Notwithstanding any other provision of law, the pharmacy license shall authorize the holder to conduct a pharmacy. The license shall be renewed annually and shall not be transferable.

(~~g~~h) Notwithstanding any other provision of law, the wholesale license shall authorize the holder to wholesale dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

(~~h~~i) Notwithstanding any other provision of law, the veterinary food-animal drug retailer license shall authorize the holder thereof to conduct a veterinary food-animal drug retailer and to sell and dispense veterinary food-animal drugs as defined in Section 4042.

(~~i~~j) For licenses referred to in subdivisions (~~f~~g), (g~~g~~h), and (~~h~~i), any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board.

~~(j) This section shall become operative on July 1, 2001.~~

§ 4207. Investigations; limitations; requests for additional information

(a) Upon receipt of an application for a license and the applicable fee, the board shall make a thorough investigation to determine whether the applicant is qualified for the license being sought. The board shall also determine whether this article has been complied with, and shall investigate all matters directly related to the issuance of the license that may affect the public welfare.

(b) The board shall not investigate matters connected with the operation of a premises other than those matters solely related to the furnishing of dangerous drugs or dangerous devices, or to the performance or provision of cognitive services, that might adversely affect the public welfare.

(c) The board shall deny an application for a license if the applicant does not qualify for the license being sought.

(d) Notwithstanding any other provision of law, the board may request any information it deems necessary to complete the application investigation required by this section, and a request for information that the board deems necessary in carrying out this section in any application or related form devised by the board shall not be required to be adopted by regulation pursuant to the Administrative Procedures Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

Alternatively, there may be simpler statutory ways to accomplish the same goal, such as the following shortened/alternative versions of B&P 4037, 4120, and 4201:

§ 4037. Pharmacy

(a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced ~~and where prescriptions are compounded~~. "Pharmacy" includes, but is not limited to:

~~,~~(1) any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail;~~.~~

(2) any area, place, or premises described in a license issued by the board wherein personnel licensed by the board engage in and/or supervise drug order/prescription review by performing functions including, but not limited to, data entry, drug utilization review, patient and/or

prescriber contact, claims submission and processing, patient profile review, and allergy and drug-interaction review;

(3) any area, place, or premises described in a license issued by the board wherein personnel licensed by the board provide cognitive pharmacy services including, but not limited to, clinical advice or information, telephonic or in-person patient consultation, drug utilization review, and medication therapy management.

(b) "Pharmacy" shall not include any area in a facility licensed by the State Department of Health Services where floor supplies, ward supplies, operating room supplies, or emergency room supplies of dangerous drugs or dangerous devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility.

(c) "Pharmacy" shall not include a clinic licensed under Section 4180 or Section 4190.

§ 4120. Nonresident pharmacies; registration; application forms; legislative intent

(a) A nonresident pharmacy shall not sell or distribute dangerous drugs or dangerous devices in this state through any person or media other than a wholesaler who has obtained a license pursuant to this chapter or through a selling or distribution outlet that is licensed as a wholesaler pursuant to this chapter without registering as a nonresident pharmacy.

(b) Applications for a nonresident pharmacy registration shall be made on a form furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of this section.

(c) Each application to conduct a nonresident pharmacy shall specify the type or types of pharmacy to be practiced on the subject premises, pursuant to Section 4037(a).

(~~c~~d) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any nonresident pharmacy.

(~~d~~e) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to serve as any evidence that the nonresident pharmacy is doing business within this state.

§ 4201. Contents of applications; fees; powers of license holders

(a) Each application to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer, shall be made on a form furnished by the board, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein.

(b) Each application to conduct a pharmacy shall specify the type or types of pharmacy to be practiced on the subject premises, pursuant to Section 4037(a).

(~~b~~c) As used in this section, and subject to subdivision (~~e~~d), the term "person beneficially interested" means and includes:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that no natural person shall be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

(~~e~~d) In any case where the applicant is a partnership or other unincorporated association, is a limited liability company, or is a corporation, and where the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (a) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

(~~d~~e) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.

(~~e~~f) Upon the approval of the application by the board and payment of the fee required by this chapter for each pharmacy, wholesaler, or veterinary food-animal drug retailer, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer, if all of the provisions of this chapter have been complied with.

(~~f~~g) Notwithstanding any other provision of law, the pharmacy license shall authorize the holder to conduct a pharmacy. The license shall be renewed annually and shall not be transferable.

(~~g~~h) Notwithstanding any other provision of law, the wholesale license shall authorize the holder to wholesale dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

(~~h~~i) Notwithstanding any other provision of law, the veterinary food-animal drug retailer license shall authorize the holder thereof to conduct a veterinary food-animal drug retailer and to sell and dispense veterinary food-animal drugs as defined in Section 4042.

(~~i~~j) For licenses referred to in subdivisions (~~f~~g), (~~g~~h), and (~~h~~i), any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board.

~~(j) This section shall become operative on July 1, 2001.~~

Alternatively, if the goal is to license as "pharmacies" facilities performing prescription review or cognitive services, but not to permit those licensed facilities to possess/store dangerous drugs or devices, i.e., to limit possession/storage of dangerous drugs and devices to only "traditional" pharmacy settings, that could be accomplished with the following versions of these statutes:

§ 4037. Pharmacy

(a) "Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced ~~and where prescriptions are compounded~~. Only a "dispensing pharmacy," as defined in subdivision (b), may possess, prepare, manufacture, derive, compound, repackage, furnish, sell or dispense controlled substances, dangerous drugs, or dangerous devices. In all other respects, whenever the term "pharmacy" is used in this chapter, it shall be deemed to refer to every one of the types in subdivision (b).

(b) "Pharmacy" includes, but is not limited to:

(1) a "dispensing pharmacy," which is any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail;

(2) a "prescription processing pharmacy", which is any area, place, or premises described in a license issued by the board wherein personnel licensed by the board engage in and/or supervise drug order/prescription review by performing functions including, but not limited to, data entry, drug utilization review, patient and/or prescriber contact, claims submission and processing, patient profile review, and allergy and drug-interaction review;

(3) an "advice/clinical center pharmacy," which is any area, place, or premises described in a license issued by the board wherein personnel licensed by the board provide cognitive pharmacy services including, but not limited to, clinical advice or information, telephonic or in-person patient consultation, drug utilization review, and medication therapy management.

(~~b~~c) "Pharmacy" shall not include any area in a facility licensed by the State Department of Health Services where floor supplies, ward supplies, operating room supplies, or emergency room supplies of dangerous drugs or dangerous devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility.

(d) "Pharmacy" shall not include a clinic licensed under Section 4180 or Section 4190.

§ 4120. Nonresident pharmacies; registration; application forms; legislative intent

(a) A nonresident pharmacy shall not sell or distribute dangerous drugs or dangerous devices in this state through any person or media other than a wholesaler who has obtained a license pursuant to this chapter or through a selling or distribution outlet that is licensed as a wholesaler pursuant to this chapter without registering as a nonresident pharmacy.

(b) Applications for a nonresident pharmacy registration shall be made on a form furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of this section.

(c) Each application to conduct a nonresident pharmacy shall specify a single type of pharmacy to be practiced on the subject premises, pursuant to Section 4037(b). There shall be a separate registration required for each type of pharmacy to be practiced.

(ed) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any nonresident pharmacy.

(~~d~~e) The Legislature, by enacting this section, does not intend a license issued to any nonresident pharmacy pursuant to this section to serve as any evidence that the nonresident pharmacy is doing business within this state.

§ 4201. Contents of applications; fees; powers of license holders

(a) Each application to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer, shall be made on a form furnished by the board, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein.

(b) Each application to conduct a pharmacy shall specify a single type of pharmacy to be practiced on the subject premises, pursuant to Section 4037(b). There shall be a separate license required for each type of pharmacy to be practiced.

(~~b~~c) As used in this section, and subject to subdivision (~~e~~d), the term "person beneficially interested" means and includes:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that no natural person shall be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

(~~c~~d) In any case where the applicant is a partnership or other unincorporated association, is a limited liability company, or is a corporation, and where the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (a) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

(~~d~~e) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.

(~~e~~f) Upon the approval of the application by the board and payment of the fee required by this chapter for each pharmacy, wholesaler, or veterinary food-animal drug retailer, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer, if all of the provisions of this chapter have been complied with.

(~~f~~g) Notwithstanding any other provision of law, the pharmacy license shall authorize the holder to conduct a pharmacy. The license shall be renewed annually and shall not be transferable.

(~~g~~h) Notwithstanding any other provision of law, the wholesale license shall authorize the holder to wholesale dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

(~~h~~i) Notwithstanding any other provision of law, the veterinary food-animal drug retailer license shall authorize the holder thereof to conduct a veterinary food-animal drug retailer and to sell and dispense veterinary food-animal drugs as defined in Section 4042.

(~~i~~j) For licenses referred to in subdivisions (~~f~~g), (~~g~~h), and (~~h~~i), any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board.

~~(j) This section shall become operative on July 1, 2001.~~

If the goal is to license "advice centers" / "prescription processing centers" as *something other than* "pharmacies," B&P 4037, 4120, and 4201 could be left unchanged in favor of the following changes to 4110, 4111, 4201, etc., and the following additional provisions:

§ 4016.5. Advice Center

"Advice center" means an area, place, or premises licensed by the board wherein personnel licensed by the board provide cognitive pharmacy services including, but not limited to, clinical advice or information, telephonic or in-person patient consultation, drug utilization review, and medication therapy management.

§ 4040.1. Prescription Processing Center

"Prescription processing center" means an area, place, or premises licensed by the board wherein personnel licensed by the board engage in and/or supervise drug order/prescription review by performing functions including, but not limited to, data entry, drug utilization review, patient and/or prescriber contact, claims submission and processing, patient profile review, and allergy and drug-interaction review.

§ 4110. Licenses; renewal; transfer; temporary permits; fees

(a) No person shall conduct a pharmacy, advice center, or prescription processing center in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy, advice center, or prescription processing center owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy, advice center, or prescription processing center in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

(b) The board may, at its discretion, issue a temporary permit, when the ownership of a pharmacy, advice center, or prescription processing center is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be established by the board at an amount not to exceed the annual fee for renewal of a permit to conduct a pharmacy, advice center, or prescription processing center. When needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal service of the notice of termination upon the permitholder or service by certified mail, return receipt requested, at the permitholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permitholder be deemed to have a vested property right or interest in the permit.

§ 4111. Issuance and renewal of licenses; persons or entities precluded; exceptions

(a) Except as otherwise provided in subdivision (b), (d), or (e), the board shall not issue or renew a license to conduct a pharmacy, advice center, or prescription processing center to any of the following:

(1) A person or persons authorized to prescribe or write a prescription, as specified in Section 4040, in the State of California.

(2) A person or persons with whom a person or persons specified in paragraph (1) shares a community or other financial interest in the permit sought.

(3) Any corporation that is controlled by, or in which 10 percent or more of the stock is owned by a person or persons prohibited from pharmacy, advice center, or prescription processing center ownership by paragraph (1) or (2).

(b) Subdivision (a) shall not preclude the issuance of a permit for an inpatient hospital pharmacy to the owner of the hospital in which it is located.

(c) The board may require any information the board deems is reasonably necessary for the enforcement of this section.

(d) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy, advice center, or prescription processing center to be owned or owned and operated by a person licensed on or before August 1, 1981, under the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code) and qualified on or before August 1, 1981, under subsection (d) of Section 1310 of Title XIII of the federal Public Health Service Act, as amended, whose ownership includes persons defined pursuant to paragraphs (1) and (2) of subdivision (a).

(e) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy, advice center, or prescription processing center to be owned or owned and operated by a pharmacist authorized to issue a drug order pursuant to subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

§ 4112.1. Nonresident advice centers; registration; prerequisites and requirements; fee; application

(a) Any advice center located outside this state that provides cognitive pharmacy services including, but not limited to, clinical advice or information, telephonic or in-person patient consultation, drug utilization review, or medication therapy management,.into this state shall be considered a nonresident advice center.
(b) All nonresident advice centers shall register with the board. The board may register a nonresident advice center that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident advice center shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are providing cognitive pharmacy services including, but not limited to, clinical advice or information, telephonic or in-person patient consultation, drug utilization review, and medication therapy management.to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

(d) All nonresident advice centers shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident advice center shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the advice center in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident advice center shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(e) All nonresident advice centers shall maintain records of cognitive pharmacy services including, but not limited to, clinical advice or information, telephonic or in-person patient consultation, drug utilization review, and medication therapy management provided.to patients or providers in this state so that the records are readily retrievable from the records of other services provided.

(f) Any advice center subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the advice center who has access to the patient's records. This toll-free telephone number shall be disclosed during each interaction with a patient or provider in this state.

(g) The registration fee shall be the fee specified in . . .

§ 4112.2. Nonresident prescription processing centers; registration; prerequisites and requirements; fee; application

(a) Any prescription processing center located outside this state that provides drug order/prescription review by performing functions including, but not limited to, data entry, drug utilization review, patient and/or prescriber contact, claims submission and processing, patient profile review, and allergy and drug-interaction review, into this state shall be considered a nonresident prescription processing center.

(b) All nonresident prescription processing centers shall register with the board. The board may register a nonresident prescription processing center that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident prescription processing center shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are providing drug order/prescription review by performing functions including, but not limited to, data entry, drug utilization review, patient and/or prescriber contact, claims submission and processing, patient profile review, and allergy and drug-interaction review to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

(d) All nonresident prescription processing centers shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident prescription processing center shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the prescription processing center in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident prescription processing center shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(e) All nonresident prescription processing centers shall maintain records of drug order/prescription review by performing functions including, but not limited to, data entry, drug utilization review, patient and/or prescriber contact, claims submission and processing, patient profile review, and allergy and drug-interaction review provided.to patients or providers in this state so that the records are readily retrievable from the records of other services provided.

(f) Any prescription processing center subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the advice center who has access to the patient's records. This toll-free telephone number shall be disclosed during each interaction with a patient or provider in this state.

(g) The registration fee shall be the fee specified in . . .

§ 4120.1. Nonresident advice centers; registration; application forms; legislative intent

(a) A nonresident advice center shall not provide cognitive pharmacy services including, but not limited to, clinical advice or information, telephonic or in-person patient consultation, drug utilization review, or medication therapy management, to or for patients or providers in this state without registering as a nonresident advice center.
(b) Applications for a nonresident advice center shall be made on a form furnished by the board. The board may require any information the board deems reasonably necessary to carry out the purposes of this section.

(c) The Legislature, by enacting this section, does not intend a license issued to any nonresident advice center pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any nonresident advice center.

(d) The Legislature, by enacting this section, does not intend a license issued to any nonresident advice center pursuant to this section to serve as any evidence that the nonresident advice center is doing business within this state.

§ 4120.2. Nonresident prescription processing centers; registration; application forms; legislative intent

(a) A nonresident prescription processing center shall not provide drug order/prescription review services by performing functions including, but not limited to, data entry, drug utilization review, patient and/or prescriber contact, claims submission and processing, patient profile review, and allergy and drug-interaction review, to or for patients or providers in this state without registering as a nonresident prescription processing center.

(b) Applications for a nonresident prescription processing center shall be made on a form furnished by the board. The board may require any information the board deems reasonably necessary to carry out the purposes of this section.

(c) The Legislature, by enacting this section, does not intend a license issued to any nonresident prescription processing center pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any nonresident prescription processing center.

(d) The Legislature, by enacting this section, does not intend a license issued to any nonresident prescription processing center pursuant to this section to serve as any evidence that the nonresident prescription processing center is doing business within this state.

§ 4125. Quality assurance program

(a) Every pharmacy, advice center, and prescription processing center shall establish a quality assurance program that shall, at a minimum, document medication errors and/or errors in provision of cognitive pharmacy services or prescription processing services attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications, or providing cognitive pharmacy services or prescription processing services, so that the pharmacy may take appropriate action to prevent a recurrence.

(b) Records generated for and maintained as a component of a pharmacy's ongoing quality assurance program shall be considered peer review documents and not subject to discovery in any arbitration, civil, or other proceeding, except as provided hereafter. That privilege shall not prevent review of a pharmacy's quality assurance program and records maintained as part of that system by the board as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the pharmacy. Nothing in this section shall be construed to prohibit a patient from accessing his or her own prescription records. Nothing in this section shall affect the discoverability of any records not solely generated for and maintained as a component of a pharmacy's ongoing quality assurance program.

~~(c) This section shall become operative on January 1, 2002.~~

§ 4201. Contents of applications; fees; powers of license holders

(a) Each application to conduct a pharmacy, wholesaler, ~~or~~ veterinary food-animal drug retailer, advice center, or prescription processing center, shall be made on a form furnished by the board, and shall state the name, address, usual occupation, and professional qualifications, if any, of the

applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein.

(b) As used in this section, and subject to subdivision (c), the term "person beneficially interested" means and includes:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that no natural person shall be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

(c) In any case where the applicant is a partnership or other unincorporated association, is a limited liability company, or is a corporation, and where the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (a) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

(d) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.

(e) Upon the approval of the application by the board and payment of the fee required by this chapter for each pharmacy, wholesaler, ~~or~~ veterinary food-animal drug retailer, advice center, or prescription processing center, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, ~~or~~ veterinary food-animal drug retailer, advice center, or prescription processing center, if all of the provisions of this chapter have been complied with.

(f) Notwithstanding any other provision of law, the pharmacy license shall authorize the holder to conduct a pharmacy. The license shall be renewed annually and shall not be transferable.

(g) Notwithstanding any other provision of law, the wholesale license shall authorize the holder to wholesale dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

(h) Notwithstanding any other provision of law, the veterinary food-animal drug retailer license shall authorize the holder thereof to conduct a veterinary food-animal drug retailer and to sell and dispense veterinary food-animal drugs as defined in Section 4042.

(i) Notwithstanding any other provision of law, the advice center license shall authorize the holder thereof to conduct an advice center and to provide cognitive pharmacy services as defined in Section 4016.5.

(j) Notwithstanding any other provision of law, the prescription processing center license shall authorize the holder thereof to conduct a prescription processing center and to provide drug order/prescription review services as defined in Section 4040.1.

(~~i~~k) For licenses referred to in subdivisions (f), (g), ~~and~~ (h), (i), and (j), any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board.

~~(j) This section shall become operative on July 1, 2001.~~

§ 4207. Investigations; limitations; requests for additional information

(a) Upon receipt of an application for a license and the applicable fee, the board shall make a thorough investigation to determine whether the applicant is qualified for the license being sought. The board shall also determine whether this article has been complied with, and shall investigate all matters directly related to the issuance of the license that may affect the public welfare.

(b) The board shall not investigate matters connected with the operation of a premises other than those matters solely related to the furnishing of dangerous drugs or dangerous devices, or to the performance or provision of advice center or prescription processing center services, that might adversely affect the public welfare.

(c) The board shall deny an application for a license if the applicant does not qualify for the license being sought.

(d) Notwithstanding any other provision of law, the board may request any information it deems necessary to complete the application investigation required by this section, and a request for information that the board deems necessary in carrying out this section in any application or related form devised by the board shall not be required to be adopted by regulation pursuant to the Administrative Procedures Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

Finally, other options would include (i) licensing such entities as "pharmacies" under the current definition(s), without revision, (ii) not licensing these entities at all, (iii) deferring the licensure of these entities to some other agency (e.g., Department of Health Services), or (iv) awaiting some consensus at the national level about interstate cooperation thereon.

None of these alternatives would apparently require statutory revision at this time.

2. Out-of-State Pharmacists (and Pharmacies)

A second primary topic for discussion has been whether and/or how to regulate those out-of-state pharmacists who provide cognitive services and/or prescription processing services to and/or for California patients and providers, particularly where those pharmacists are doing so not through affiliation with or employment by a licensed entity (e.g., nonresident pharmacy, advice center, or prescription processing center), but on a consulting or other non-site-specific basis. During all of the Committee's discussion(s) of this issue, there has been acknowledgment of a need to balance the Board's primary duty to protect the public with its desire not to impede either patient access to services (particularly for California patients) or to squeeze pharmacists out of the marketplace.

This issue has not arisen directly in the past, with regard to out-of-state pharmacists filling and/or dispensing prescription drugs, because until now those out-of-state pharmacists have worked in (or at least this has been the assumption) nonresident pharmacies that were themselves required to maintain licensure. So there has not previously been a perceived need to consider licensing out-of-state pharmacists separately (in California) from the entities in which they practice. Now, however, there apparently has been or may be an industry growth in the number of pharmacists in other states providing services to California patients or providers who are not permanently or indivisibly affiliated with any particular (licensed) premises. This seems particularly likely with regard to cognitive/prescription processing services, which due to imaging/file-sharing advances, are not nearly as tied to a particular "place" as are (or were) dispensing functions.
Secondary and tertiary considerations arise from this discussion as well, including: whether to limit the requirement of California licensure to out-of-state pharmacists providing cognitive or prescription processing services, or to extend it to those dispensing medications as well; whether to require this licensure of all pharmacists providing such services to California patients and/or providers, or only those not affiliated with a licensed entity of some kind; whether to put primary responsibility for record-keeping pertaining to provision of services to California patients on the shoulders of a licensed entity, or on the shoulders of the pharmacist (whether or not licensed in California); and/or if out-of-state pharmacists are not required to be licensed in California, how best to enforce violations of (particularly, California) law committed by those pharmacists.

The wide-ranging discussion at the March and June 2005 meetings has seemed to acknowledge a possibility of choosing between (this list is not exhaustive or exclusive, only reflective of those options primarily discussed) (a) licensing all out-of-state pharmacists, (b) requiring out-of-state pharmacists to maintain some form of registration short of licensure, (c) licensing only entities under the auspices of which out-of-state pharmacists would (be required to) practice, and/or (d) requiring that the pharmacists-in-charge of these licensed entities also be licensed in California.

The March 2005 draft statutory chose a combination of (a), (c), and (d), requiring licensure for all out-of-state pharmacists providing cognitive services or prescription processing services to California, and *also* requiring licensure of the pharmacist-in-charge of a nonresident pharmacy. This was accomplished through amendments to B&P 4051(c) and (d), 4112(e) and (g), and 4113.

§ 4051. ~~Dangerous drugs and devices~~Pharmacy practice

(a) The holder of a valid, unexpired pharmacist license issued by the board is vested with the authority and responsibility to perform the following functions inherent to pharmacy practice:

(1) Interpreting, verifying, and implementing drug orders and prescriptions;
(2) Dispensing pursuant to legitimate drug orders and prescriptions;
(3) Ensuring proper drug storage, documentation, labeling and record-keeping;
(4) Maintaining accurate, complete, and confidential patient profiles and records;
(5) Supervising pharmacy technicians and other ancillary personnel in the pharmacy;
(6) Designing and implementing quality assurance procedures and protocols;
(7) Compounding drug products pursuant to prescription and for prescriber office use;
(8) Maintaining safe, secure, and sanitary conditions in licensed premises;
(9) Performing cognitive services, including drug utilization reviews and management, medication therapy reviews and management, and patient counseling and consultation;
(10) Collaborating with prescribers and other care providers regarding patient care;
(11) Implementing standardized procedures and protocols regarding patient care;
(12) Administering or furnishing drugs or biologicals where permitted by law;
(13) Initiating, adjusting, or implementing patient drug regimens where permitted by law; and
(14) Such other pharmacy functions as are authorized by this chapter.

(~~a~~b) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist licensed under this chapter.

(c) Except as otherwise provided in this chapter, it is unlawful for any person to perform any prescription review, consultation, drug utilization review, medication therapy management, or other cognitive services for, pertaining to, or at the request of, patients, prescribers, or other care providers in this state, unless he or she is a pharmacist licensed under this chapter.

(~~b~~d) Notwithstanding any other law, a pharmacist licensed under this chapter may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide cognitive services, clinical advice or information, or patient consultation, if all of the following conditions are met:

(1) The cognitive service, clinical advice or information, or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription records, patient profiles, or other relevant medical information for purposes of cognitive services, patient and clinical consultation, and advice, and appropriately reviews that information before performing any of these functions.~~,~~

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

(4) A pharmacist authorizing the initiation or adjustment of a prescription, providing clinical advice or information or patient consultation outside the premises of a licensed pharmacy shall

maintain the patient records or other patient-specific information used in those activities in a readily retrievable form and provide those records to the board upon request. These records or information shall be preserved for a period of at least three years from the date they were relied upon or consulted by for the purposes of performing any such function.

§ 4112. Nonresident pharmacies; registration; prerequisites and requirements; fee; application; contact lenses

(a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state, and/or that performs prescription review, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state, shall be considered a nonresident pharmacy.

(b) All nonresident pharmacies shall register with the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

(d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(e) All nonresident pharmacies shall comply with Section 4113.

(ef) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

(g) Any prescription review, consultation, drug utilization review, medication therapy management, or other cognitive services performed by a nonresident pharmacy for, pertaining to, or at the request of, patients, prescribers, or other care providers in this state, may only be performed by a pharmacist licensed under this chapter.

(~~f~~h) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(~~g~~i) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state . The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.

(~~h~~j) The registration fee shall be the fee specified in subdivision (a) of Section 4400.

~~(i) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.~~
(~~j~~k) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

§ 4113. Pharmacists-in-charge; designation; responsibilities; notifications

(a) Every pharmacy shall designate a pharmacist-in-charge, and shall not operate as a pharmacy without a designated pharmacist-in-charge. ~~and w~~Within 30 days ~~thereof~~of a new or replacement designation, the pharmacy shall ~~notify~~ submit an application for approval of this designation to the board stating in writing ~~of~~ the identity and license number of ~~that~~ the designated pharmacist-in-charge, ~~pharmacist~~ and the date he or she was designated. The designated pharmacist-in-charge must have a valid, unexpired pharmacist license issued by the board. Where a designated pharmacist-in-charge has been denied a license, had a license revoked, suspended, or placed on probation, or is the subject of an ongoing board investigation into possible unprofessional conduct, the board may prospectively refuse or retroactively withdraw its approval of the designation and require that the pharmacy designate another pharmacist-in-charge.

(b) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

(c) Every pharmacy shall notify the board within 30 days of the date when a pharmacist ceases to be a pharmacist-in-charge. This duty is separate from and additional to that stated in subpart (a).

There has been concern expressed at the March and June 2005 meetings that this requirement of licensure would be burdensome to nonresident pharmacies and out-of-state pharmacists. Various other options were discussed at the meetings such as a "registration program" for the nonresident pharmacist, some type of national license certification by the National Association of Boards of Pharmacy (NABP), reciprocity, and/or no additional licensure but a requirement that the out-of-state pharmacist meet California practice standards. Another possibility would be striking the requirement that the individual practitioner be licensed in California, instead requiring that the out-of-state pharmacist providing services (or drugs) to California patients practice under the auspices of an entity licensed as a nonresident pharmacy (or other form of site license), with a possible further requirement that the pharmacist-in-charge be a California licensee.

As was discussed at the June 2005 Committee meeting, NABP model rules would require that a pharmacist providing telepharmacy services across state lines identify himself or herself to any patient as a "licensed pharmacist," notify patients of the jurisdiction in which he/she is currently licensed to practice pharmacy, and register (with relevant state boards) to practice telepharmacy across state lines and provide patients with the jurisdiction's Board address and phone number.

Among the above-listed alternatives to requiring licensure of all out-of-state pharmacists (or at least out-of-state PICs) that have been discussed, two are presented herein in possible statutory form: (1) the possibility of a non-licensure "certification" of some sort (perhaps supported by NABP), which would require conformance to California standards; and (2) the possibility that licensure would not be required of out-of-state pharmacists so long as services delivered to any California patient were delivered under the auspices of a California-licensed pharmacy/entity.

First, possible draft language for the "certification" alternative:

§ 4018.5. Certified out-of-state pharmacist

"Certified out-of-state pharmacist" means and includes a pharmacist licensed in good standing by another state who has applied for and received a certification of status from the board.

§ 4051. ~~Dangerous drugs and devices~~Pharmacy practice

(a) The holder of a valid, unexpired pharmacist license issued by the board is vested with the authority and responsibility to perform the following functions inherent to pharmacy practice:

(1) Interpreting, verifying, and implementing drug orders and prescriptions;
(2) Dispensing pursuant to legitimate drug orders and prescriptions;
(3) Ensuring proper drug storage, documentation, labeling and record-keeping;
(4) Maintaining accurate, complete, and confidential patient profiles and records;
(5) Supervising pharmacy technicians and other ancillary personnel in the pharmacy;
(6) Designing and implementing quality assurance procedures and protocols;
(7) Compounding drug products pursuant to prescription and for prescriber office use;
(8) Maintaining safe, secure, and sanitary conditions in licensed premises;
(9) Performing cognitive services, including drug utilization reviews and management, medication therapy reviews and management, and patient counseling and consultation;

(10) Collaborating with prescribers and other care providers regarding patient care;
(11) Implementing standardized procedures and protocols regarding patient care;
(12) Administering or furnishing drugs or biologicals where permitted by law;
(13) Initiating, adjusting, or implementing patient drug regimens where permitted by law; and
(14) Such other pharmacy functions as are authorized by this chapter.

(~~a~~b) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber to a patient in this state unless he or she is a pharmacist licensed under this chapter or is a certified out-of-state pharmacist pursuant to Section 4200.6.

(c) Except as otherwise provided in this chapter, it is unlawful for any person to perform any prescription review, consultation, drug utilization review, medication therapy management, or other cognitive services for, pertaining to, or at the request of, patients, prescribers, or other care providers in this state, unless he or she is a pharmacist licensed under this chapter or is a certified out-of-state pharmacist pursuant to Section 4200.6.

(~~b~~d) Notwithstanding any other law, a pharmacist licensed under this chapter or a certified out-of-state pharmacist may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide cognitive services, clinical advice or information, or patient consultation, if all of the following conditions are met:

(1) The cognitive service, clinical advice or information, or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist or certified out-of-state pharmacist has access to prescription records, patient profiles, or other relevant medical information for purposes of cognitive services, patient and clinical consultation, and advice, and appropriately reviews that information before performing any of these functions.~~,~~

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

(4) A pharmacist or certified out-of-state pharmacist authorizing the initiation or adjustment of a prescription, providing clinical advice or information or patient consultation outside the premises of a licensed pharmacy shall maintain the patient records or other patient-specific information used in those activities in a readily retrievable form and provide those records to the board upon request. These records or information shall be preserved for a period of at least three years from the date they were relied upon or consulted by for the purposes of performing any such function.

§ 4112. Nonresident pharmacies; registration; prerequisites and requirements; fee; application; contact lenses

(a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state, and/or that performs

prescription review, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state, shall be considered a nonresident pharmacy.

(b) All nonresident pharmacies shall register with the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

(d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(e) All nonresident pharmacies shall comply with Section 4113.

(ef) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

(g) Any prescription review, consultation, drug utilization review, medication therapy management, or other cognitive services performed by a nonresident pharmacy for, pertaining to, or at the request of, patients, prescribers, or other care providers in this state, may only be performed by a pharmacist licensed under this chapter or by a certified out-of-state pharmacist.

(fh) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(gi) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state . The board shall not adopt any regulations that require face-to-

face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.

(~~h~~j) The registration fee shall be the fee specified in subdivision (a) of Section 4400.

~~(i) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.~~

(~~j~~k) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

§ 4200.6. Certified out-of-state pharmacist; qualifications; proof; fees

(a) The board may certify as a certified out-of-state pharmacist any applicant who meets all the following requirements:

(1) Is at least 18 years of age.

(2) Has a pharmacist license in good standing issued by another state in the United States.

(3) Provides a certification of his or her licensure in good standing from the state(s) of licensure [and/or a certification of licensure in good standing from the NABP].

(4) Affirms, under penalty of perjury, his or her knowledge of the requirements of California law pertaining to pharmacy, agrees to abide by and/or be bound by California performance standards, and acknowledges that any violation thereof shall lead to revocation of this certification.

(b) Proof of the qualifications of an applicant for certification as a certified out-of-state pharmacist, shall be made to the satisfaction of the board and shall be substantiated by affidavits or other evidence as may be required by the board.

(c) Each person, upon application for certification as a certified out-of-state pharmacist under this chapter, shall pay to the executive officer of the board, the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

(d) Any certification issued hereunder shall expire after two years, and may only be renewed by subsequent application for renewal. Any applicant for renewal must meet all of the requirements for an initial applicant for certification as stated by this section.

(e) Any application for initial certification or renewal is subject to denial on any of the grounds for denial of any other license issued by the board.

(f) Any certification issued hereunder is subject to suspension, revocation, or other discipline on any of the grounds for discipline against any other license issued by the board.

Second, possible draft language for the "affiliation" requirement:

§ 4051. ~~Dangerous drugs and devices~~Pharmacy practice

(a) The holder of a valid, unexpired pharmacist license issued by the board is vested with the authority and responsibility to perform the following functions inherent to pharmacy practice:
(1) Interpreting, verifying, and implementing drug orders and prescriptions;
(2) Dispensing pursuant to legitimate drug orders and prescriptions;
(3) Ensuring proper drug storage, documentation, labeling and record-keeping;
(4) Maintaining accurate, complete, and confidential patient profiles and records;
(5) Supervising pharmacy technicians and other ancillary personnel in the pharmacy;
(6) Designing and implementing quality assurance procedures and protocols;
(7) Compounding drug products pursuant to prescription and for prescriber office use;
(8) Maintaining safe, secure, and sanitary conditions in licensed premises;
(9) Performing cognitive services, including drug utilization reviews and management, medication therapy reviews and management, and patient counseling and consultation;
(10) Collaborating with prescribers and other care providers regarding patient care;
(11) Implementing standardized procedures and protocols regarding patient care;
(12) Administering or furnishing drugs or biologicals where permitted by law;
(13) Initiating, adjusting, or implementing patient drug regimens where permitted by law; and
(14) Such other pharmacy functions as are authorized by this chapter.
(a~~b~~) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber to a patient in this state unless he or she is a pharmacist licensed under this chapter or is a pharmacist performing any of these functions while employed by or as an owner, officer, principal or agent of a pharmacy or a nonresident pharmacy licensed under this chapter.

(c) Except as otherwise provided in this chapter, it is unlawful for any person to perform any prescription review, consultation, drug utilization review, medication therapy management, or other cognitive services for, pertaining to, or at the request of, patients, prescribers, or other care providers in this state, unless he or she is a pharmacist licensed under this chapter or is a pharmacist performing any of these functions while employed by or as an owner, officer, principal or agent of a pharmacy or a nonresident pharmacy licensed under this chapter.

(~~b~~d) Notwithstanding any other law, a pharmacist licensed under this chapter or functioning as an employee, owner, officer, principal, or agent of a pharmacy or a nonresident pharmacy licensed under this chapter may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide cognitive services, clinical advice or information, or patient consultation, if all of the following conditions are met:

(1) The cognitive service, clinical advice or information, or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist licensed under this chapter or functioning as an employee, owner, officer, principal, or agent of a pharmacy or a nonresident pharmacy licensed under this chapter has access to prescription records, patient profiles, or other relevant medical information for purposes of cognitive services, patient and clinical consultation, and advice, and appropriately reviews that information before performing any of these functions.~~.~~

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

(4) A pharmacist licensed under this chapter or a pharmacist functioning as an employee, owner, officer, principal, or agent of a pharmacy or a nonresident pharmacy licensed under this chapter, in authorizing the initiation or adjustment of a prescription, or in providing clinical advice or information or patient consultation outside the premises of a licensed pharmacy, shall maintain the patient records or other patient-specific information used in those activities in a readily retrievable form and provide those records to the board upon request. These records or information shall be preserved for a period of at least three years from the date they were relied upon or consulted by for the purposes of performing any such function.

§ 4112. Nonresident pharmacies; registration; prerequisites and requirements; fee; application; contact lenses

(a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state, and/or that performs prescription review, patient consultation, drug utilization review, medication therapy management, or other cognitive pharmacy services for patients in this state,~~-~~shall be considered a nonresident pharmacy.

(b) All nonresident pharmacies shall register with the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

(d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(e) All nonresident pharmacies shall comply with Section 4113.

(ef) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

(g) Any prescription review, consultation, drug utilization review, medication therapy management, or other cognitive services performed by a nonresident pharmacy for, pertaining to, or at the request of, patients, prescribers, or other care providers in this state, may only be performed by a pharmacist licensed under this chapter or by a pharmacist who is an employee, owner, officer, principal, or agent of the nonresident pharmacy.

(fh) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(gi) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state . The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.

(hj) The registration fee shall be the fee specified in subdivision (a) of Section 4400.

~~(i) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.~~

(jk) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

3. Definition of "Pharmacy Practice"

The third and final primary topic for discussion has been whether and/or how to amend or expand statutory definition(s) of practice as a pharmacist to (i) better conform to existing practice, (ii) emphasize the professional development of pharmacy, and/or (iii) maximize the potential for California pharmacist practice reimbursement under Medicare Part D.

The statutory proposals pertaining to this subject area made along with the others for the March 2005 Licensing Committee meeting have not generated comment on specifics of the proposed language so much as they have inspired discussion about whether (and how) it is a good idea to expand and/or specify the practice definitions in this way. Therefore, what follows is a verbatim reiteration of those statutory amendments pertaining to this subject that were presented in March 2005. Except as already specified above, at least some of these (particularly revisions to B&P 4052, which essentially just reduce the size of section 4052 and relocate subparts to sections 4052.1-4052.3) seem non-controversial. Others have not yet been fully debated.

In brief, the idea behind many of these suggested amendments/revisions is to recognize in statute that the practice of pharmacy means far more than simply counting and dispensing medications, that it is a professional practice, and that it can be practiced both within and without the four walls of a traditional pharmacy, by licensed professional pharmacists.

§ 4036. Pharmacist

"Pharmacist" means a natural person to whom a license has been issued by the board, under Section 4200, except as specifically provided otherwise in this chapter. The holder of a valid, unexpired pharmacist license issued by the board is entitled to practice pharmacy as defined by this chapter, within or outside of a licensed pharmacy as authorized by this chapter.

§ 4050. Professional status

(a) In recognition of and consistent with the decisions of the appellate courts of this state, the Legislature hereby declares the practice of pharmacy to be a profession.

(b) Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. Pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities.

§ 4051. ~~Dangerous drugs and devices~~Pharmacy practice

(a) The holder of a valid, unexpired pharmacist license issued by the board is vested with the authority and responsibility to perform the following functions inherent to pharmacy practice:

(1) Interpreting, verifying, and implementing drug orders and prescriptions;
(2) Dispensing pursuant to legitimate drug orders and prescriptions;
(3) Ensuring proper drug storage, documentation, labeling and record-keeping;
(4) Maintaining accurate, complete, and confidential patient profiles and records;
(5) Supervising pharmacy technicians and other ancillary personnel in the pharmacy;
(6) Designing and implementing quality assurance procedures and protocols;
(7) Compounding drug products pursuant to prescription and for prescriber office use;
(8) Maintaining safe, secure, and sanitary conditions in licensed premises;
(9) Performing cognitive services, including drug utilization reviews and management, medication therapy reviews and management, and patient counseling and consultation;
(10) Collaborating with prescribers and other care providers regarding patient care;
(11) Implementing standardized procedures and protocols regarding patient care;
(12) Administering or furnishing drugs or biologicals where permitted by law;
(13) Initiating, adjusting, or implementing patient drug regimens where permitted by law; and
(14) Such other pharmacy functions as are authorized by this chapter.

(~~a~~b) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist licensed under this chapter.

(c) Except as otherwise provided in this chapter, it is unlawful for any person to perform any prescription review, consultation, drug utilization review, medication therapy management, or other cognitive services for, pertaining to, or at the request of, patients, prescribers, or other care providers in this state, unless he or she is a pharmacist licensed under this chapter.

(~~b~~d) Notwithstanding any other law, a pharmacist licensed under this chapter may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide cognitive services, clinical advice or information, or patient consultation, if all of the following conditions are met:

(1) The cognitive service, clinical advice or information, or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription records, patient profiles, or other relevant medical information for purposes of cognitive services, patient and clinical consultation, and advice, and appropriately reviews that information before performing any of these functions.~~,~~

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

(4) A pharmacist authorizing the initiation or adjustment of a prescription, providing clinical advice or information or patient consultation outside the premises of a licensed pharmacy shall maintain the patient records or other patient-specific information used in those activities in a readily retrievable form and provide those records to the board upon request. These records or information shall be preserved for a period of at least three years from the date they were relied upon or consulted by for the purposes of performing any such function.

§ 4052. Power to perform procedures and functions; training

(a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded ~~medication~~ drug product to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform ~~the following~~ procedures or functions in a licensed health care facility as authorized by Section 4052.1. ~~in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:~~

~~(A) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.~~

~~(B) Ordering drug therapy-related laboratory tests.~~

~~(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).~~

~~(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.~~

(5)~~(A)~~ Perform ~~the following~~ procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2. ~~in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):~~

~~(i) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.~~

~~(ii) Ordering drug therapy-related laboratory tests.~~

~~(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).~~

~~(iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.~~

~~(B) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.~~

~~(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:~~

~~(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.~~

~~(ii) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.~~

~~(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.~~

~~(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.~~

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide cognitive services such as drug utilization review, medication therapy management, consultation to patients, and professional information, including clinical or pharmacological information, advice, or consultation, to other health care professionals.

(8)~~(A)~~ Furnish emergency contraception drug therapy ~~in accordance with either of the following~~as authorized by Section 4052.3.~~:~~

(9) Administer immunizations under the supervision of a prescriber.

~~(i) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.~~

~~(ii) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.~~

~~(B) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.~~

~~(C) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.~~

~~(D) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this paragraph.~~

~~(b)(1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.~~

~~(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A) successfully completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.~~
~~(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs~~

~~with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.~~

(b~~e~~) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(c~~d~~) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(d~~e~~) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

§ 4052.1. Performance of procedures or functions in a licensed health care facility; requirements

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order ~~(the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility)~~.

(4) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(b) Prior to performing any procedure authorized by this section, a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

§ 4052.2. Performance of procedures or functions authorized by other providers; requirements

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts

with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (c):

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order ~~(the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility)~~.

(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(c) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:

(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(4) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an

approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(d) Prior to performing any procedure authorized by this section, a pharmacist shall have either (1) successfully completed clinical residency training or (2) demonstrated clinical experience in direct patient care delivery.

§ 4052.3. Furnishing emergency contraception drug therapy; requirements

(a) Notwithstanding any other provision of law, a pharmacist furnish emergency contraception drug therapy in accordance with either of the following:

(1) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(2) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.

(b) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(c) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(d) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this section.

(e) For each emergency contraception drug therapy initiated pursuant to this section, the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

§ 4052.4~~1~~. Skin puncture

Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for himself or herself, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

§ 4306.5. Acts or omissions constituting unprofessional conduct

(a) Unprofessional conduct for a pharmacist may include:

(1) ~~a~~Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board;

(2) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment and/or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices and/or with regard to the provision of cognitive services;

(3) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

(b) For pharmacists who practice outside of a pharmacy premises, unprofessional conduct may include acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

ATTACHMENT G

September 21, 2005

Licensing Committee
California State Board of Pharmacy
400 R Street, Ste 4070
Sacramento, CA 95814

Re: Development of Proposal for Pharmacy Performing Drug Utilization Review, Medication Therapy Management, Pharmacist Call Centers and Central Processing of Prescription Drugs for CA Patients

Dear Licensing Committee:

The California Pharmacists Association (CPhA) is providing comments regarding the above referenced subject which was set forth in a memorandum from the Licensing Committee dated June 3, 2005. While we understand that no formal action on this subject has been approved by the Board, we feel it is appropriate to submit comments to the memorandum so that the Licensing Committee and the Board as a whole can consider them in connection with further action on the subject.

From our review of the memorandum and its attachments, we understand that the Licensing Committee is attempting to develop a statutory scheme for regulating the practice of pharmacy beyond traditional dispensing activities. The proposed language appears to suggest that the avenue to achieve this is to expand the definition of a "pharmacy" to include any physical location at which a pharmacist conducts activities requiring licensure.

CPhA recognizes the Board's desire to address the appropriate regulation of the practice of pharmacy as it expands into areas distinct from handling and dispensing of drugs. However, CPhA does not believe that changing the definition of pharmacy is an appropriate and effective means of regulating those activities.

As the Board is aware, traditionally, pharmacies are facilities where dangerous drugs are stored, compounded and dispensed. Record keeping, supervision and other requirements related to the normal activities carried out at pharmacies are based on the storage and dispensing of drugs at that physical location. If the definition were expanded as set forth in the proposed language, then the regulatory scheme for a pharmacist would have to be applied to locations where a pharmacist would be acting within his/her scope of practice, unrelated to dispensing, storage, etc. However, the regulatory scheme for a pharmacy would make no sense when applied to locations where storage and dispensing does not occur. Indeed, this would cause substantial confusion for the profession, and might actually deter licensees from engaging in more comprehensive cognitive services because of the uncertainty of how they are

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regulated. Indeed, this could have the affect of deterring pharmacists from providing these services, leaving other health care professionals to fill the vacuum.

CPhA believes there is a more appropriate and effective approach to regulating non dispensing activities of pharmacists. Although we do not agree that the need for such language has been shown, we also believe there is a way to regulate non resident pharmacists providing services to California residents in a manner that is more effective and legally sustainable than the approach contained in the Board's proposal.

Based on the foregoing, CPhA recommends abandoning consideration of the statutory changes attached to the June 3rd memorandum. Instead, CPhA requests that the Board consider the alternative approach that is attached to this letter. We believe the attachment appropriately addresses the need to regulate non dispensing activities of pharmacists, including regulating the activities of pharmacists licensed outside California when those pharmacists are providing services to California residents.

Sincerely,

John A. Cronin, Pharm.D., J.D.
Senior Vice President and General Counsel

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Article 2.5 is added to the Business and Professions Code to read:

Article 2.5. Requirements for Pharmacists Providing Cognitive Pharmacy Services.

Section 4044. Except as otherwise provided in this chapter, it is unlawful for any person to perform any cognitive pharmacy services for, or pertaining to, or at the request of patients, prescribers, or other care providers in this state unless he or she is licensed or registered under this chapter. A pharmacist providing cognitive therapy services, as set forth in section 4045, shall comply with all of the requirements of this Article.

Section 4045. (a) The following definitions govern the provisions of this Article.

(1) "Pharmacist" means either a person issued a license by the board under section 4200, or a person registered under section 4047.

(2) "Cognitive pharmacy services" include clinical advice or information, telephonic or in-patient consultation, drug utilization review and medication therapy management, whether or not provided in a licensed pharmacy.

Section 4046. A pharmacist providing cognitive pharmacy services shall do all of the following:

(a) Comply with the provisions of section 4051.

(b) Document reports by patients and health care providers of adverse outcomes or consequences associated with the delivery of cognitive pharmacy services.

(C) Document medication errors occurring in connection with or discovered as a result of the delivery of cognitive pharmacy services.

(d) Maintain for a period of three years patient records related to the delivery of cognitive pharmacy services and other patient specific information in a readily retrievable form.

Section 4047. (a) It shall be unlawful for any individual residing outside the state to provide cognitive pharmacy service to an individual residing in the state unless the person registers as set forth in this section.

(b) Before an individual residing outside the state may provide cognitive pharmacy services to residents of the state the person shall register with the board as a non resident provider of cognitive pharmacy services. The board shall promulgate regulations governing the forms and procedures for registration.

(C) In order to qualify to register as a non resident provider of cognitive pharmacy services, a person must provide proof of licensure as a pharmacist in good standing in the state form which the services will be provided to California residents, and the entity on whose behalf the services will be provided. In addition, the person must execute a declaration provided by the board acknowledging that all services provided to California residents are subject to the provisions of this chapter and the regulations of the board, and that any material violation of the provisions of this chapter, the regulations of the board or conduct deemed by the board to be unprofessional is grounds for revocation of registration and the right to provide services to California residents.

ATTACHMENT H

California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

LICENSING COMMITTEE
Meeting Summary

DATE: June 15, 2005

TIME: 9:30 p.m. – 3:00 p.m.

LOCATION: Hilton Oakland Airport
One Hegenberger Road
Oakland, CA 94621

BOARD MEMBERS Ruth Conroy, Pharm.D., Chair
Clarence Hiura, Pharm.D.
John Jones, RPh, JD

STAFF PRESENT: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Dennis Ming, Supervising Inspector

Jan Perez, Legislative Coordinator
Joshua Room, Deputy Attorney General

Call to Order

Committee Chair Ruth Conroy called the meeting to order at 9:30 a.m.

Request from University Compounding Pharmacy to Require Licensure of all Pharmacists that Compound

Pharmacist Joe Grasela representing University Compounding Pharmacy requested that the Licensing Committee consider a requirement that all compounding pharmacies have a special compounding license. He stated that the sterile compounding license has been in place for two years and it has raised the quality of compounded products available to the public. He is suggesting that a special license be required for pharmacies whether they compound injectable sterile products or non-sterile products.

Mr. Grasela explained that this special compounding license for pharmacies is necessary to protect the public. He stated that capsules can do as much harm as injectables. Creams

improperly used containing lidocaine can cause cardiac arrest. Oral inhalations, solutions and eye drops can be contaminated. Many other non-compounded non-sterile products can cause harm as an improperly made sterile product.

He also felt that by requiring this special compounding pharmacy license, California would be leading the way and demonstrating to the federal Food and Drug Administration (FDA) that California is regulating compounding pharmacies contrary to FDA's contention that Boards of Pharmacy are not doing enough in this area.

Pharmacist Grasela also stated that by having a special compounding pharmacy license, the board would be creating a new specialty of pharmacy. This new compounding specialty will be similar to nuclear pharmacy, home health care pharmacy, and hospital pharmacy and will provide credibility to the public and provide access to products that cannot be made by manufacturers.

The committee expressed concern regarding the compounding of inhalation and ophthalmic drug products. It was noted that both the original legislation and regulation proposals regarding sterile compounding included inhalation and ophthalmic drug products; however, because of the opposition, the legislation and regulations were limited only to compounded sterile injectable drug products.

It was explained that last year, the board's Workgroup on Compounding drafted legislation and regulations to govern compounding, which the board approved. While the bill, AB 595, was stalled this year due to opposition from the Department of Health Services (DHS), the board will eventually move forward with the regulations. The committee noted that the regulations are comprehensive and provide regulatory oversight for all compounded drug products, which includes training requirements of all pharmacy personnel who compound and a quality assurance component that guarantees that the compounded drug product meets the specified criteria of strength and quality. It was noted that the workgroup did not discuss whether a special license for all pharmacies that compounded was necessary to protect the public; however, it was the board's position that the legislative and regulatory proposals were important consumer measures and will continue to pursue them actively.

It was the committee's recommendation not to support the request that the board require a special license for all pharmacies that compound drug products and advised Mr. Grasela that the professional association may want to sponsor such legislation, at which time the board would take a position. Any proposal to require a special license would have a fiscal impact on the board and licensees. Pharmacies would have to pay an additional license fee of $500, and the board would be required to add more staff, if the same opening and annual inspection requirements were continued.

Temporary Pharmacy Permit for Pharmacies that Compound Injectable Sterile Drug Products

Chair Ruth Conroy explained that a pharmacy that compounds injectable sterile drug products is required to have a specialized pharmacy permit in addition to being licensed as a pharmacy. Under current law, when a pharmacy changes ownership, the board has the authority to issue a temporary pharmacy permit during the transition from the previous owner to the new owner. However, this same provision was not included for the injectable sterile compounding pharmacies. This has caused some difficulties for pharmacies that can obtain a temporary pharmacy permit for their general pharmacy practice, but cannot obtain temporary permit for the compounding of sterile injectable sterile products. Thus, the pharmacy must cease this service until the change of ownership is completed.

The committee recommended that the board sponsor an omnibus provision next year to allow for the issuance of a temporary pharmacy permit when a change of ownership occurs for pharmacies that compound injectable sterile drug products.

Request for Board Recognition of the School of Pharmacy at Touro University

Chair Conroy stated that Touro University College of Pharmacy is requesting that the Board of Pharmacy recognize its school of pharmacy for purposes of approving intern applications for its 64 students in the Class of 2009.

Current regulation, 16 CCR § 1719, states that a "recognized school of pharmacy" means a school accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education (ACPE). Touro University currently has pre-candidate statues.

The committee recommended that the board recognize Touro University College of Pharmacy.

Pharmacist Self-Assessment Mechanism (PSAM)

At the last Licensing Committee meeting, the committee discussed the announcement by the National Association of Boards of Pharmacy (NABP) regarding the development of the PSAM. The PSAM is an evaluation tool intended to assist pharmacists in obtaining objective, non-punitive feedback on their knowledge base and is available on NABP's web site.

The PSAM is applicable to general pharmacy practitioners in all practice settings. It consists of 100 multiple-choice questions and is divided into three sections of equal length. Each section can be completed in as little as one hour, but a maximum of three hours per section is allowed. Pharmacists may take all three sections in one setting, or complete one section at a time, but once a section is begun it must be completed in its entirety. All three sections must be completed within 30 days of when pharmacists complete the first section. The fee for PSAM is $75.

During the meeting in June, the committee learned that the Idaho State Board of Pharmacy would grant 4 hours of Board-approved CE to pharmacists for completing the PSAM. More recently, Tennessee will grant 3 hours of CE. NABP did pursue accreditation of the PSAM by the Accreditation Council for Pharmacy Education (ACPE), but the accreditation was denied. It was also suggested by the California Pharmacists Association (CPhA) that the Pharmacy

Foundation of California approve the PSAM as another CE option for California pharmacists. However, it not clear whether or not CPhA had pursued this suggestion.

The committee recommended that a pharmacist that completes the PSAM be granted 6 hours of continuing education.

Request for Comments on the Definition of Pharmacist's Scope of Practice Consistent with Pharmacy Law for Disaster Response Teams

Assistant Executive Officer Virginia Herold stated that since 2005, a group of individuals from various state and local agencies and some private associations have been meeting to design an advance registration system to prescreen and identify medical providers for quick deployment in response to disasters and bioterrorism events.

The group has been meeting under the authority of the state Emergency Medical Services Authority under a Health Resources and Service Administration Hospital Bioterrorism grant. This project is the "Emergency System for Advanced Registration of Volunteer Health Professionals" (ESAR-VHP). She stated that she has been participating as the board's representative.

One item that has been requested is the scope of practice for pharmacists in emergency situations. She and Supervising Inspector Robert Ratcliff have developed a preliminary scope of practice that they seek comment and input.

The final version will state in layperson's terms the duties pharmacists can perform under emergency conditions. For example, a draft version of the emergency scope of practice for dentists envisions the ability to suture outside the mouth or set bones in faces.

The committee was provided a draft and suggested revisions were provided.

Request from the Accreditation Council for Pharmacy Education (ACPE) for Comments by November 1, 2005 on the Draft PharmD Standards and Guidelines

The Licensing Committee was provided a copy of the revised ACPE standards and guidelines. ACPE is requesting comments by November 1, 2005.

Development of Proposal to Update the Definition and Requirements for Pharmacy, Nonresident Pharmacy, Pharmacist Practice and Licensure of Out-of-State Pharmacists

Since December 2004, the Licensing Committee has been working to respond to inquiries and comments pertaining to the scope of practice of pharmacy, particularly to the practice of pharmacy outside of a traditional pharmacy setting, and to the provision of services to California patients by pharmacies, pharmacists, and ancillary staff outside state lines.

The committee agreed to address these issues through its quarterly meetings. However, the committee was encouraged to develop a concrete proposal sooner rather than later in anticipation of the implementation of provisions of the Medicare Modernization Act (MMA) addressing pharmacists' services within the Medication Therapy Management Programs (MTMP) of the Medicare Act, which are expected to take effect in 2006.

Following an initial overview document prepared for the December 2004 meeting, a draft of proposed statutory changes was prepared for the March 2005 meeting. That draft was the basis for discussions and reactions at the March and June 2005 meetings.

Based on discussions and feedback at the March and June 2005 meetings, liaison counsel with the Attorney General's Office, DAG Joshua Room drafted statutory changes to frame the previous discussions in terms of the various policy choices presented. As always, the primary concern for the board is protection of the California public.

As the committee has defined and discussed them, there are three primary areas in which further specification and possible statutory change has been debated: (1) Given what has been or may be an increase in the number of entities/premises, both within California and outside of California, that are mostly focusing on "prescription review" and/or "cognitive services" separate from and/or in the absence of traditional "pharmacy" tasks such as the actual filling of prescriptions and dispensing of drugs, what can or should the Board do to license those entities/premises, as "pharmacies" or otherwise; (2) When those "review" or "cognitive" services are provided by out-of-state pharmacies or pharmacists to California patients, particularly when out-of-state pharmacists are not located in a licensed premises, should the Board require that: the out-of-state pharmacist have a California license, or an alternative California registration; that the pharmacist at least be affiliated with an entity, i.e., a "pharmacy," that is licensed in California; that out-of-state "pharmacies," however defined, have a PIC licensed in California; and/or should the Board depend on discipline by pharmacists' (and pharmacies') home states of licensure to ensure compliance; (3) In order to conform California law to federal expectations, to permit California licensees to practice fully as professional pharmacists, and/or to maximize the opportunities available under Medicare Part D, should the definitions and scope of practice of pharmacy presently stated in Pharmacy Law be expanded and/or further specified by the Board?

The committee was provided with possible responses that were not intended to be comprehensive.

1. Definition of "Pharmacy"

One of the primary topics of Committee discussion has been, in light of the apparently increased emphasis on provision of professional "cognitive services" (e.g., DUR, MTM) by pharmacists, which may or may not be provided out of a traditional "pharmacy" premises: (a) whether to license facilities, in California or outside of California, from which such services are provided (which do not otherwise fit the traditional definition of a "pharmacy") *at all*; and (b) if so, whether to license them as "pharmacies," some variant thereof, or as something else entirely.

The draft statutory proposal prepared for the March 2005 meeting assumed that facilities in which "pharmacy" was being practiced (whether "pharmacy" as in prescription-filling, or "pharmacy" as in consultation, MTMP, etc.) would need to be licensed as pharmacies. It identified three separate *types* of pharmacies for licensure: (i) "Intake/dispensing" pharmacies - traditional pharmacies; (ii) "Prescription processing" pharmacies - offering prescription review services for another pharmacy or other provider; and (iii) "Advice/clinical center" pharmacies – providing clinical/cognitive services directly to patients or providers. It also provided for "nonresident pharmacies" that could be any of these three types. The draft assumed that the three (four) types would not be mutually exclusive, i.e., a given facility could overlap. Various statutory options were provided that accomplished the same goal.

There was considerable discussion and opposition to requiring California licensed pharmacists to be licensed as an "Advice/clinical center pharmacy." It was emphasized that the board needs to recognize the independent practice of pharmacists and this proposal doesn't. The public is adequately protected by the pharmacist licensure.

It was also questioned why the board requires an entity that processes prescriptions to be licensed as a pharmacy. It was explained that the processing of prescriptions under current pharmacy law constitutes the practice of pharmacy and therefore, must be practiced in a licensed pharmacy. It is the location that would receive telephonic and electronic orders for prescriptions and maintain the prescription and patient information, directing the prescription to a particular pharmacy for filling and dispensing. While the pharmacy law authorizes a pharmacist to electronically enter a prescription or order into a pharmacy's or hospital's computer, the law doesn't allow other pharmacy personnel to process prescriptions under the supervision of a pharmacist. To allow such a practice outside a pharmacy would require explicit language. An option may be to allow the practice pursuant to a contract with a pharmacy as long as the original prescriptions records and record of the pharmacist's review be maintained by the filling pharmacy.

Another option provided was to license the facilities but not call them "pharmacies." Other options included (i) licensing such entities as "pharmacies" under the current definition(s), without revision, (ii) not licensing these entities at all, (iii) deferring the licensure of these entities to some other agency (e.g., Department of Health Services), or (iv) awaiting some consensus at the national level about interstate cooperation thereon. None of these alternatives would require statutory revisions.

2. Out-of-State Pharmacists (and Pharmacies)

A second primary topic for discussion has been whether and/or how to regulate those out-of-state pharmacists who provide cognitive services and/or prescription processing services to and/or for California patients and providers, particularly where those pharmacists are doing so not through affiliation with or employment by a licensed entity (e.g., nonresident pharmacy, advice center, or prescription processing center), but on a consulting or other non-site-specific basis. During all of the Committee's discussion(s) of this issue, there has been acknowledgment of a need to balance

the Board's primary duty to protect the public with its desire not to impede either patient access to services (particularly for California patients) or to squeeze pharmacists out of the marketplace.

This issue has not arisen directly in the past, with regard to out-of-state pharmacists filling and/or dispensing prescription drugs, because until now those out-of-state pharmacists have worked in (or at least this has been the assumption) nonresident pharmacies that were themselves required to maintain licensure. So there has not previously been a perceived need to consider licensing out-of-state pharmacists separately (in California) from the entities in which they practice. Now, however, there apparently has been or may be an industry growth in the number of pharmacists in other states providing services to California patients or providers who are not permanently or indivisibly affiliated with any particular (licensed) premises. This seems particularly likely with regard to cognitive/prescription processing services, which due to imaging/file-sharing advances, are not nearly as tied to a particular "place" as are (or were) dispensing functions.

Secondary and tertiary considerations arise from this discussion as well, including: whether to limit the requirement of California licensure to out-of-state pharmacists providing cognitive or prescription processing services, or to extend it to those dispensing medications as well; whether to require this licensure of all pharmacists providing such services to California patients and/or providers, or only those not affiliated with a licensed entity of some kind; whether to put primary responsibility for record-keeping pertaining to provision of services to California patients on the shoulders of a licensed entity, or on the shoulders of the pharmacist (whether or not licensed in California); and/or if out-of-state pharmacists are not required to be licensed in California, how best to enforce violations of (particularly, California) law committed by those pharmacists.

The wide-ranging discussion at the March and June 2005 meetings has seemed to acknowledge a possibility of choosing between (this list is not exhaustive or exclusive, only reflective of those options primarily discussed) (a) licensing all out-of-state pharmacists, (b) requiring out-of-state pharmacists to maintain some form of registration short of licensure, (c) licensing only entities under the auspices of which out-of-state pharmacists would (be required to) practice, and/or (d) requiring that the pharmacists-in-charge of these licensed entities also be licensed in California.

The March 2005 draft statutory chose a combination of (a), (c), and (d), requiring licensure for all out-of-state pharmacists providing cognitive services or prescription processing services to California, and *also* requiring licensure of the pharmacist-in-charge of a nonresident pharmacy.

Concern was expressed at the March and June 2005 meetings that this requirement of licensure would be burdensome to nonresident pharmacies and out-of-state pharmacists. Various other options were discussed at the meetings such as a "registration program" for the nonresident pharmacist, some type of national license certification by the National Association of Boards of Pharmacy (NABP), reciprocity, and/or no additional licensure but a requirement that the out-of-state pharmacist meet California practice standards. Another possibility would be striking the requirement that the individual practitioner be licensed in California, instead requiring that the out-of-state pharmacist providing services (or drugs) to California patients practice under the auspices of an entity licensed as a nonresident pharmacy (or other form of site license), with a possible further requirement that the pharmacist-in-charge be a California licensee.

As was discussed at the June 2005 Committee meeting, NABP model rules would require that a pharmacist providing telepharmacy services across state lines identify himself or herself to any patient as a "licensed pharmacist," notify patients of the jurisdiction in which he/she is currently licensed to practice pharmacy, and register (with relevant state boards) to practice telepharmacy across state lines and provide patients with the jurisdiction's Board address and phone number.

Among the above-listed alternatives to requiring licensure of all out-of-state pharmacists (or at least out-of-state PICs) that have been discussed, two were presented as possible statutory form: (1) the possibility of a non-licensure "certification" of some sort (perhaps supported by NABP), which would require conformance to California standards; and (2) the possibility that licensure would not be required of out-of-state pharmacists so long as services delivered to any California patient were delivered under the auspices of a California-licensed pharmacy/entity.

The California Pharmacists Association (CPhA) provided a similar proposal that would require an out-of-state pharmacist providing cognitive pharmacy services to register as a nonresident provider of pharmacy services.

The third and final primary topic for discussion has been whether and/or how to amend or expand statutory definition(s) of practice as a pharmacist to (i) better conform to existing practice, (ii) emphasize the professional development of pharmacy, and/or (iii) maximize the potential for California pharmacist practice reimbursement under Medicare Part D.

The statutory proposals pertaining to this subject area made along with the others for the March 2005 Licensing Committee meeting have not generated comment on specifics of the proposed language so much as they have inspired discussion about whether (and how) it is a good idea to expand and/or specify the practice definitions in this way. Therefore, the committee was provided with a verbatim reiteration of those statutory amendments pertaining to this subject that were presented in March 2005. Except as already specified above, at least some of these (particularly revisions to B&P 4052, which essentially just reduce the size of section 4052 and relocate subparts to sections 4052.1-4052.3) seem non-controversial. Others have not yet been fully debated.

In brief, the idea behind many of these suggested amendments/revisions is to recognize in statute that the practice of pharmacy means far more than simply counting and dispensing medications, that it is a professional practice, and that it can be practiced both within and without the four walls of a traditional pharmacy, by licensed professional pharmacists.

The committee discussed this final section and there was support for these changes and updates to pharmacy law. It was suggested that this section be separated from the first two sections of the proposal and be pursued legislatively.

The committee agreed to continue discussion of the proposal at the December Licensing Committee meeting. The committee will report to the board at the October meeting the progress of its discussions.

Adjournment

Licensing Committee Chair Ruth Conroy thanked everyone for participating and adjourned the meeting at 3:00 p.m.

ATTACHMENT I

Board of Pharmacy Licensing Statistics - Fiscal Year 2005/06

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
APPLICATIONS													
Received													
Pharmacist (exam applications)	79	153	117										349
Pharmacist (initial licensing applications)	32	439	149										620
Intern pharmacist	35	234	232										501
Pharmacy technician	369	558	609										1536
Pharmacy	39	36	30										105
Sterile Compounding	14	10	1										25
Clinics	5	5	1										11
Hospitals	1	2	0										3
Nonresident Pharmacy	2	7	5										14
Licensed Correctional Facility	0	0	0										0
Hypodermic Needle and Syringes	0	1	0										1
Out of State Distributor	7	7	5										19
Wholesalers	2	19	2										23
Veterinary Food-Animal Drug Retailer	0	0	0										0
Exemptees	26	61	51										138
Issued													
Pharmacist	146	334	161										641
Intern pharmacist	42	140	272										454
Pharmacy technician	438	569	491										1498
Pharmacy	45	42	31										118
Sterile Compounding	5	5	12										22
Clinics	15	8	7										30
Hospitals	1	5	0										6
Nonresident Pharmacy	9	3	7										19
Licensed Correctional Facility	0	0	0										0
Hypodermic Needle and Syringes	0	3	0										3
Out of State Distributor	10	13	5										28
Wholesalers	5	5	5										15
Veterinary Food-Animal Drug Retailer	0	0	0										0
Exemptees	42	47	33										122

Board of Pharmacy Licensing Statistics - Fiscal Year 2005/06

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pending													
Pharmacist Examination			u/a										
Intern pharmacist	u/a	u/a	218										
Pharmacy technician	u/a	u/a	83										
Pharmacy	49	43	42										42
Sterile Compounding	69	74	63										63
Clinics	51	48	42										42
Hospitals	11	8	8										8
Nonresident Pharmacy	29	33	31										31
Licensed Correctional Facility	0	0	0										0
Hypodermic Needle and Syringes	8	6	6										6
Out of State Distributor	80	74	74										74
Wholesalers	51	65	62										62
Veterinary Food-Animal Drug Retailer	0	0	0										0
Exemptees	116	130	148										148
Change of Pharmacist-in-Charge													
Received	72	128	128										328
Processed	102	92	97										291
Pending	209	245	276										276
Change of Exemptee-in-Charge													
Received	2	2	0										4
Processed	2	2	0										4
Pending	8	8	8										8
Change of Permits													
Received	33	73	39										145
Processed	21	50	48										119
Pending	171	194	184										184
Discontinuance of Business													
Received	17	17	9										43
Processed	30	1	0										31
Pending	39	55	64										64

Board of Pharmacy Licensing Statistics - Fiscal Year 2005/06

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Renewals Received													
Pharmacist	1019	3078											4097
Pharmacy technician	1279	3553											4832
Pharmacy	591	592											1183
Sterile Compounding	11	44											55
Clinics	60	126											186
Nonresident Pharmacy	21	26											47
Hypodermic Needle and Syringes	20	35											55
Out of State Distributor	26	52											78
Wholesalers	25	97											122
Veterinary Food-Animal Drug Retailer	1	3											4
Exemptees	111	320											431

The data for renewals received for September is not yet available.

ATTACHMENT J

State of California Department of Consumer Affairs

Memorandum

To: Board of Pharmacy Date: October 18, 2005

From: Patricia F. Harris
Executive Officer

Subject: Competency Committee Report

1. Content Outline for the CPJE

The board recently completed its job analysis of the pharmacist profession for purposes of validating the licensure examination. This analysis is done every five years. The job analysis identifies the skills, frequency and importance of tasks performed by pharmacists. From these skill statements, the Competency Committee develops a content outline for the examination. All questions for the examination are developed according to this outline.

In late November 2004, the board mailed a job analysis questionnaire to 3,000 California pharmacists. By the deadline for submission (December 31, 2004), approximately 1,200 responses were received (a 40 percent return response).

The pharmacists surveyed by the board were asked to identify the tasks that they perform, and the frequency and the importance of the tasks. The responses were tallied by the board's examination consultant and were analyzed by the Competency Committee. The Competency Committee then created a new content outline for board approval. A copy of the new outline will be provided for your approval at the board meeting.

Before the new content outline will be implemented, it will be released publicly so that candidates can prepare for the examination. The board's CPJE content outline does not include tasks tested by NAPLEX; these tasks were removed via analysis of the NAPLEX content outline.

2. Results of the California Pharmacy Jurisprudence Examination (CPJE)

Periodically, the Board of Pharmacy performs quality assurance assessments to ensure the appropriateness of the CPJE. The board initiated such a study on September 1, 2005. To assure the thoroughness of this assessment, 400 individuals will needed for participation. Once 400 people have taken the CPJE, release of examination scores should resume on a weekly basis, usually within 14 days of the time a candidate takes

the examination. It is anticipated the results will be released by November 1, 2005 (which is earlier than last year.)

3. Release of Exam Results

The board releases examination statistics twice a year (April and October). The examination results for 2004/05 will be released around November 1. The release of the results is important to the schools to access the performance of their graduates. The board will place the results on our Web site and send to the schools. The pass rate for the CPJE for 2004/05 was 77 percent.

4. New Contract Underway for Administration of the California Pharmacy Jurisprudence Examination

The board's CPJE is administered through Experior Assessments, LLC, at test centers nationwide. Experior also administers California examinations for many other boards and programs of the Department of Consumer Affairs. There is a master contract for these test administration services, which is a convenience to all departmental entities because we do not each need to go out to bid for separate test administration contracts. This master contract ends November 30, 2005.

Previously, staff reported that the Department of Consumer Affairs had been preparing a request for proposals (RFP) for test administration services for the future. The successful vendor will provide test administration services for the department's entities for the next five years. Due to delays in the RFP process, the department was able to secure a one-year extension on the current contract until November 30, 2006.

ATTACHMENT K

Licensing Committee

2005-2006
First Quarter Report
July 1, 2005 – September 30, 2005

Goal 2: **Ensure the professional qualifications of licensees.**

Outcome: **Qualified licensees.**

Objective 2.1: **Issue licenses within three working days of a completed application by June 30, 2006.**

Measures: **Percentage of licenses issued within 3 working days.**

A new tracking system has been implemented.

Tasks:

1. **Review 100 percent of all applications within 7 working days of receipt.**

   Note: Foreign graduate applications are not being processed (with a few exceptions) because of the changes outlined in SB 1913. Upon completion of the procedures and revision of the necessary forms, the board will resume this workload.

	Apps. Received:				**Average Days to Process:**			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Pharmacist (exam applications)	234*				12.5			
Pharmacist (initial licensing)	471*				4.1			
Pharmacy Intern	269*				8			
Pharmacy Technicians	927*				8			
Pharmacies	108				11			
Non-Resident Pharmacy	14				9			
Wholesaler	23				16			
Veterinary Drug Retailer	0				0			
Exemptee	138				6			
Out-of-State Distributor	19				19			
Clinics	11				13			
Hypo Needle & Syringe	1				1			
Sterile Compounding	25				2			

*Denotes July and August 2005 information available at time of report development.

2. **Process 100 percent of all deficiency documents within 3 working days of receipt.**

Average days to process deficiency:

	Q1	Q2	Q3	Q4
Pharmacist (exam applications)	1-3			
Pharmacist (initial licensing)	1-3			
Pharmacy Intern	7			
Pharmacy Technicians	10			
Pharmacies	4			
Non-Resident Pharmacy	9			
Wholesaler	4			
Veterinary Drug Retailer	0			
Exemptee	1			
Out-of-State Distributor	4			
Clinics	2			
Hypo Needle & Syringe	1			

3. **Make a licensing decision within 3 working days after all deficiencies are corrected.**

Average days to issue license:

	Q1	Q2	Q3	Q4
Pharmacist (exam applications)	3-5			
Pharmacist (initial licensing)	3-5			
Pharmacy Intern	5			
Pharmacy Technicians	5			
Pharmacies	3			
Non-Resident Pharmacy	5			
Wholesaler	5			
Veterinary Drug Retailer	0			
Exemptee	2			
Out-of-State Distributor	5			
Clinics	6			
Hypo Needle & Syringe	2			

4. **Issue professional and occupational licenses to those individuals and firms that meet minimum requirements.**

	Q1	Q2	Q3	Q4
Pharmacist	641			
Pharmacy Intern	454			
Pharmacy Technician	1498			
Pharmacies	5			
Non-Resident Pharmacy	8			
Wholesaler	6			
Veterinary Drug Retailer	0			
Exemptee	2			
Out-of-State Distributor	14			
Clinics	1			
Hypo Needle & Syringe	1			
Sterile Compounding	1			

5. **Withdrawn licenses to applicants not meeting board requirements.**

	Q1	Q2	Q3	Q4
Pharmacy Technician	0			
Pharmacies	0			
Non-Resident Pharmacy	6			
Clinics	0			
Sterile Compounding	0			
Exemptees	23			
Hypo Needle & Syringe	1			
Out-of-State Distributor	6			
Wholesaler	5			

Objective 2.2: **Implement at least 50 changes to improve licensing decisions by June 30, 2006.**

Measure: **Number of implemented changes.**

Tasks:

1. **Review Pharmacist Intern Program.**

9/04 *Governor signed SB 1913 that contained new intern provisions to become effective 1/05.*

9/04 *Licensing Committee recommended changes to 1728 to implement SB 1913.*

9/04 *Licensing Committee recommended a change to 1719 to register interns who are enrolled in a school of pharmacy that has been granted "candidate status" by ACPE.*

9/04 *Licensing Committee recommended omnibus change to 1726 consistent with SB 1913.*

12/04 *Revised application and instructions to reflect changes from SB 1913 effective 1/1/05.*

10/05 *Revisions to 1719, 1720, 1726, 1727, and 1728 became effective. Regulation changes were necessary to implement SB 1915.*

2. Implement changes to the Pharmacy Technician Program.

1/04 *a. Use PTCB as a qualifying method for registration. – Completed.*

1/04 *b. Change education qualifications from A.A. degree in health science to A.A. degree in Pharmacy Technology. – Completed.*

9/04 *c. Eliminate clerk-typist from pharmacist supervisory ratio. Completed – regulation approved by OAL, change effective 10/3/04.*

9/04 *Enforcement Committee recommended technical changes to the regulatory requirements for pharmacy technicians.*

10/04 *Board approved the recommendation and will sponsor legislation in 2005.*

3/05 *SB 1111 (B&P Committee) was introduced.*

3. Administer a pharmacist licensure exam more than twice a year.

3/04 *Completed – CA applications began taking the NAPLEX and CPJE.*

9/05 *849 California applicants have taken the NAPLEX and 799 have taken the CPJE since July 1, 2005.*

4. Assist applicants in preparing to take the California pharmacist licensure examination by developing (or fostering the development of) educational programs and information on how to prepare for the pharmacist exam and by requesting that outside agencies (schools of pharmacy and private educational organizations) develop exam workshops that prepare applicants for the California Pharmacist Exam.

5. Develop statutory language to give the Board of Pharmacy the authority to grant waivers for innovative, technological and other practices to enhance the practice of pharmacy and patient care that would have oversight by an independent reviewing body during the study.

6. Continuously review and develop written exams to ensure they fairly and effectively test the knowledge, skills and abilities of importance to the practice of pharmacy in California.

8/04 *Competency Committee met for two days and developed questions as well as the job analysis.*

9/04 *Competency Committee met for two days and developed questions.*

9/04 *Reported that board will recruit for new competency committee members in its next newsletter (scheduled for November).*

10/04 *Competency Committee met for two days and developed questions.*

11/04 *Job analysis will be released.*

12/04 *Job analysis released to 3,000 pharmacists.*

1/05 *Competency Committee met for two days and developed questions.*

2/05 *Competency Committee met for two days and developed questions.*

4/05 *Competency Committee met for two days and developed questions.*

8/05 *Competency Committee met for two days and developed questions as well as developed the updated Content Outline as a result of the job analysis.*

9/05 *Competency Committee met for two days and developed questions and reviewed the final draft of the Content Outline developed at the August Retreat. Committee forwarded Content Outline to the board for approval.*

7. Implement the sterile compounding pharmacy licensing requirements by July 1, 2003.

6/04 *Completed*

9/04 *OAL approved the sterile compounding regulations and will become effective 10/29/04. The clean room requirements will take effect 7/1/05.*

9/04 *Reported that 13 sterile compounding licensed have been issued since July 1, 2004.*

1/05 *Reported that 29 sterile compounding licenses have been issued since July 1, 2004.*

6/05 *Reported that 56 sterile compounding licenses have been issued since July 1, 2004.*

9/05 *Reported that 24 sterile compounding licenses have been issued since July 1, 2005.*

8. Issue temporary permits whenever change of ownership occurs.

9/05 *1st Quarter – 28 temporary permits issued.*

9. Establish means for licensee to renew permits on line.

8/04 *Submitted Applicant Tracking System (ATS) report to the department.*

11/04 *Met with the department to discuss conversion to ATS and department prioritization.*

8/05 *Staff begin working with programmers to define business processes for ATS system. Participate in bi-weekly meetings with programmer detailing business requirements.*

9/05 *Staff continue bi-weekly meetings with programmer detailing business requirements.*

9/05 *Staff attend demonstrations for software and programs to allow for on-line renewal and applications.*

10/05 *Staff complete definition of business process and cashiering procedures with programmer for ATS.*

10. Implement Changes to Facilities Licensure Requirements

9/04 *Governor signed SB 1913 that included application requirements for all applicants.*

9/04 *Governor signed SB 1307 and AB 2682 to clarify the licensure of wholesale and non-resident wholesale facilities.*

9/04 *Staff with legal counsel reviewed application process for wholesalers and non-resident wholesalers.*

1/05 *New application forms are available for nonresident wholesalers.*

1/05 *New application forms are available for wholesalers.*

2/05 *Initiate review of clinic application requirements.*

3/05 *Initiate review of community pharmacy application requirements.*

3/05 *Initiate implementation of the surety bond requirement.*

6/05 *Submitted proposed change to clinic application requirement.*

8/05 *Staff complete draft forms to implement surety bond requirements for wholesalers and out of state distributors.*

9/05 *Staff begin working with consultant to modify existing system to accommodate changes in wholesaler and out of state distributor requirements.*

9/05 *Initiate review of pharmacy application requirements.*

9/05 *Initiate review of licensed sterile compounding application requirements.*

10/05	*Staff revise surety bond form. Form submitted to the Office of the Attorney General for approval.*
	11. Review the Ownership of Pharmacies
7/04	*Counsel provided guidance on applicants who have prescriber spouses and/or a prescriber who shares a financial interest.*
	12. Review the law regarding candidates who fail the pharmacist licensure exam 4 times or more who are required to take an additional 16 units of pharmacy education.
7/04	*Draft report provided to the board.*
9/04	*Governor signed SB 1913 to extend statutory provision to the board's next Sunset review date (2007).*
9/04	*Licensing Committee recommended omnibus regulation change to update section 1725 regarding acceptable pharmacy coursework for these candidates.*
12/04	*Report provided to the Legislature.*
	13. Evaluate application requirements for all licenses.
9/04	*Governor signed SB 1913 that gives the board clear authority to request information needed to evaluate the qualifications of any applicant.*
9/04	*Licensing Committee recommended regulation changes to implement SB 1913 related to application process for the pharmacist licensure exam (1720).*
9/04	*Licensing Committee recommended a legislative change to eliminate the rules of professional conduct required with each application.*
9/04	*Licensing Committee recommended omnibus legislative changes to Business and Professions Code 4053, 4127.5, 4205, 4206 and 4400.*
9/04	*Licensing Committee recommended changes to 1706.2 to require an eligible applicant to take the licensure exam within 1 year and obtain a license within 1 year of passing the exams.*
9/04	*Licensing Committee recommended a change to 1719 that authorizes an applicant to sit for the pharmacist licensure exam who has graduated from a pharmacy school granted "candidate" status by ACPE.*
10/04	*Board approved statutory proposal to eliminate the rules of professional conducted required for each application and omnibus changes to Business and Professions Code 4053, 4127.5, 4205, 4206 and 4400.*

12/04	*Revised application and instructions to reflect changes from SB 1913 effective 1/1/05.*
3/05	*SB 1111 (B&P) introduced that contains statutory changes to eliminate "Rules of Professional Conduct."*
10/05	*Regulation changes to 1706.2 and 1719 became effective.*
	14. Review the law regarding the educational requirements of graduates from foreign pharmacy schools.
9/04	*Governor signed SB 1913 that requires a foreign pharmacy school graduate to be certified by the Foreign Pharmacy Graduate Examination Committee.*
9/04	*Licensing Committee recommended that board amend its regulation to eliminate the foreign graduate evaluation application process and fee.*
9/04	*Sent a letter to all pending foreign graduates advising of law change and suspending application process.*
12/04	*Sent letter to all foreign graduate exam applicants not certified about revised exam eligibility status.*
10/05	*Regulation change to 1720.1 became effective. Regulation change necessary to implementation of SB 1913.*
	15. Review the law regarding continuing education (CE) requirements for pharmacists.
7/04	*Board approved recommendations from the Pharmacy Foundation of California to update the CE statute and regulation.*
9/04	*Licensing Committee recommended changes to the CE statute to relocate from regulation the 30-hour requirement, to exempt all newly licensed pharmacist from CE requirements for two years and to renew the pharmacists license as "inactive" when a pharmacist fails to certify their CE credits.*
9/04	*Licensing Committee recommended revisions to the CE regulations.*
10/04	*Board approved recommended statutory and regulatory revisions to CE requirements.*
1/05	*SB 1111 (B&P) introduced that contains CE provision.*
6/05	*Reviewed the Pharmacist Self-Assessment Mechanism (PSAM) available from the National Association of Boards of Pharmacy (NABP) and determine options for pharmacists to obtain CE for completing the assessment. Determined what other competency assessments that available.*

9/05 *Licensing Committee recommended 6 hours of CE for completing PSAM.*

10/05 *Revised CE regulations became effective.*

16. Review the license of city and county jails and juvenile facilities.

8/04 *Staff met with Board of Corrections to discuss the dispensing process at these facilities and the regulatory structure, which have no effect of law.*

17. Review the certification process for foreign graduates that was implemented 1/05 and the Test of Spoken English (TSE requirement).

3/05 *Licensing Committee discussed the certification process and TSE requirement. Requested TSE presentation at future board meeting.*

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18. Implement a temporary permit for a sterile compounding pharmacy.

9/05 *Submitted proposed statutory changes to Licensing Committee. Licensing Committee recommended board approval.*

19. Review the license of pharmacies in correctional facilities.

7/05 *Staff met with the Department of Corrections to discuss the distributions and dispensing process at these facilities and the regulatory structure of Pharmacy Law.*

20. Review the licensure requirements for clinics.

3/05 *Proposal submitted to update the license requirements for clinics.*

6/05 *Licensing Committee recommended approval of statutory changes.*

7/05 *Board approved statutory changes to clinic requirements.*

21. Review the request from University of Touro School of Pharmacy to be board recognized.

9/05 *Licensing Committee recommended approval to recognize University of Touro School of Pharmacy.*

22. Participate in the Accreditation Council for Pharmacy Education (ACPE) evaluation of California schools of pharmacy.

1/05 *Board Member Ruth Conroy participated in the ACPE review of Loma Linda University School of Pharmacy.*

2/05 *Board Member Ken Schell participated in the ACPE review of UC San Diego School of Pharmacy.*

	4/05	*Board Member Dave Fong participated in the ACPE pre-candidate review of University of Touro.*
Objective 2.3:		**Evaluate five emerging public policy initiatives affecting pharmacists' care or public safety by June 30, 2006.**
Measure:		**Number of public policy initiatives evaluated.**
Tasks:		**1. Explore the need to regulate pharmacy benefit managers.**
	10/03	*Board concluded not to regulate PBMs.*
	9/04	*Governor vetoed AB 1960 which would have required the regulation of PBMs by the Department of Managed Health Care.*
	1/05	*AB 78 introduced to define PMBs and require specified disclosures to purchases.*
	9/05	*Governor vetoed AB 78.*
		2. Explore the need to regulate drugs labeled for "veterinary use only."
	9/03	*SB 175 was introduced and signed (Chaptered 250, Statutes 2003).*
	1/04	*Completed.*
		3. Explore the importation of drugs from foreign countries.
	7/04	*Discussed at July Board meeting.*
	9/04	*Discussed at September Enforcement Committee meeting.*
	9/04	*Governor vetoed SB 1449 which would have required the board to approve Web sites for Canadian pharmacies.*
	10/04	*Discussed at October board meeting.*
	12/04	*Discussed at December Enforcement Committee meeting.*
	12/04	*HHS released its report of the Task Force on Drug Importation.*
	1/05	*Discussed at January board meeting.*
	3/05	*Discussed at March Enforcement Committee Meeting.*
	4/05	*Discussed at April board meeting.*
	6/05	*Discussed at June Enforcement Committee Meeting.*
	7/05	*Discussed at July board meeting.*

9/05	*Discussed at September Enforcement Committee Meeting.*
	4. Develop language and pursue a regulation change to allow the central fill of medication orders for inpatient hospital pharmacies.
9/04	*OAL approved regulation change and will take effect 10/22.*
10/04	*Completed.*
	5. Establish a workgroup with DHS-State Food and Drug on pharmacy compounding
9/04	*Held third meeting of workgroup on compounding – proposed draft concept on general compounding.*
12/04	*Held fourth meeting of workgroup on compounding – recommending statutory proposal.*
12/04	*Licensing Committee recommended approval of statutory proposal to define general compounding and regulatory parameters.*
1/05	*Board approved general compounding proposal.*
2/05	*AB 595 was introduced and sponsored by the board.*
8/05	*AB 595 opposed by DHS – negotiating amendments.*
	6. Approve a statewide protocol for emergency contraception (ec) to permit pharmacists to furnish ec pursuant SB 490 (Chapter 651, Statutes of 2003.)
7/04	*Protocol on Web site.*
7/04	*Board approved regulation on protocol.*
9/04	*Regulation submitted to OAL for approval.*
11/04	*OAL approved regulation, which became effective 12/04.*
11/04	*Completed.*

7. Establish a regulatory structure to authorize the dispensing of drugs by veterinarian schools.

9/04 *Governor signed SB 1913 that provides authority.*

8. Consider a waiver pursuant to CCR, Title 16, Section 1706.5 from Cedars-Sinai Medical Center (CSMC) to conduct a study with UCSF, School of Pharmacy to determine the impact of using technician check technicians to fill unit dose cassettes on patient care.

4/04 *Board approved waiver for two years.*

7/05 *CSMC presented preliminary results of the study.*

9. Development of Proposal for Pharmacist Performing DUR, Medication Therapy Management, Pharmacist Call Centers and Central Processing of Prescriptions for CA patients.

12/04 *Licensing Committee discussed concepts related to proposal.*

3/05 *Licensing Committee discussed draft and proposal.*

6/05 *Licensing Committee discussed draft and proposal.*

9/05 *Licensing Committee discussed draft and proposal.*

Objective 2.4:	**Cashier 100 percent of all application and renewal fees within two working days of receipt by June 30, 2006.**
Measure:	**Percentage of cashiered application and renewal fees within 2 working days.**
Tasks:	**1. Cashier application fees.**
9/05	*1st Quarter - The average processing time for processing new application fees is 2-3 working days.*
	2. Cashier renewal fees.
9/03	*The board lost its renewal cashier in October 2001 and has been unsuccessful in obtaining a freeze waiver to fill this position. The average processing time for processing renewal fees in house is 10 days.*
8/04	*Held interviews for renewal cashier because hiring freeze was lifted.*
10/04	*Filled vacancy for renewal cashier.*
9/05	*1st Quarter - Average processing time for central cashiering is 2-3 weeks.*
10/05	*Staff attend a user group meeting and discuss concern about processing time for central cashiering.*
Objective 2.5:	**Respond to 95 percent of all requests for verification of licensing information within 5 working days by June 30, 2006.**
Measure:	**Percentage response for verifying licensing information within 5 working days.**
Tasks:	**1. Respond to requests for licensing verification.**
9/05	*1st Quarter – Processed 223 license verifications.*
Objective 2.6:	**Update 100 percent of all information changes to licensing records within 5 working days by June 30, 2005.**
Measure:	**Percentage of licensing records changes within 5 working days**
Tasks:	**1. Make address and name changes.**
9/05	*1st Quarter – Processed 1,241 address changes.*
	2. Process discontinuance of businesses forms and related components.
9/05	*1st Quarter – Processed 31 discontinuance- of-business forms. Processing*

time is 30 days.

3. **Process changes in pharmacist-in-charge and exemptee-in-charge.**

9/05 *1st Quarter – Processed 291 pharmacist-in-charge changes. Average processing time is 14days. Processed 4 exemptee-in-charge changes. The average processing time is 5 days.*

4. **Process off-site storage applications.**

9/05 *Processed 14 off-site storage applications.*

5. **Process change-of-permit applications.**

9/05 *1st Quarter – Processed 119 applications. Average processing time is 30 days.*